Agency for Toxic Substances and Disease Registry

Division of Health Studies

Soil-Pica, Soil-Ingestion and Health Outcome Investigation: Site-Specific Health Activities

Vasquez Boulevard Interstate-70 Denver, Colorado

FINAL REPORT

MAY 2005

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
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Agency for Toxic Substances and Disease Registry
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ATLANTA, GA

SOIL-PICA, SOIL-INGESTION AND HEALTH OUTCOME INVESTIGATION: SITE-SPECIFIC HEALTH ACTIVITIES

VASQUEZ BOULEVARD INTERSTATE-70
DENVER, COLORADO

SUBMITTED BY

DISEASE CONTROL AND ENVIRONMENTAL EPIDEMIOLOGY
COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT
DENVER, COLORADO

MAY 2005

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DISCLAIMER

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ABSTRACT

Objective
To assess soil-contact activity and exposure of children to lead and arsenic in soils contaminated by metal smelters at the VBI-70 Superfund site in northwest Denver.

Methods
We conducted a door-to-door survey of 3,978 households to identify those with children aged 6 months to 6 years. We conducted interviews with parents or caretakers of participating children to determine the amount of time they played outside and the locations of play areas. The locations of play areas were identified and recorded with maps generated by a geographic information system (GIS), facilitating the linkage of the type and duration of activities with concentrations of lead and arsenic measured in soils. From eligible children, we collected fingerstick samples of blood for analysis of lead concentrations and urine samples for determination of arsenic concentrations.

Results
We identified 1,650 households with one or more eligible children. For our final analysis we selected only those individuals that gave information on all play activity areas, had completed, in-full, an interview, and provided either a blood or urine sample; preferably both. Of the 977 blood samples collected from the subjects chosen for analysis, 5.6% (55) had blood lead concentrations greater than or equal to10 µg/dL. Upon confirmatory testing 2.4% (23) of the samples remained elevated. Of the 848 urine samples collected for arsenic, 0.94% (8) were above 30 µg/L. No samples tested greater than or equal to 30 µg/L upon confirmatory testing. Results from 983 interviews indicate that 72.5% of children played with dirt; 50.4% ate or drank while playing outside; 48.7% put objects in their mouths while playing outside, and 9.1% had eaten dirt at some time in the past.

Conclusions
Our data indicate that blood lead concentrations are similar to those reported in other urban areas with houses painted with lead-based paint. The data also suggest that soil contact has not resulted in unusually high arsenic exposures.

I. BACKGROUND

Historically, the Vasquez Boulevard Interstate-70 (VBI-70) site was a major smelting center for the Rocky Mountains and the West. Three smelting plants, Omaha-Grant, Argo, and Globe, began operating in the area during the 1870's, refining gold, silver, copper, lead and zinc. Only the Globe plant (now named the Asarco Smelter) is still in operation today, refining high-purity metals.

In July 1997, the Colorado Department of Public Health and Environment (CDPHE) collected 25 soil samples from residential yards in the Elyria and Swansea neighborhoods (located inside the boundaries of the VBI-70 site). Lead levels were as high as 660 parts per million and 1,800 parts per million for soil arsenic. To further characterize the extent of contamination, the U.S. Environmental Protection Agency (EPA) collected several thousand soil samples from approximately 1,500 properties in the area during Phase I and II field investigations in the spring and summer of 1998. Composite samples of soil from the front and back yards of twenty-one (1.4%) properties had arsenic and/or lead concentrations greater than the established action levels (400 mg/kg for arsenic, soil concentration greater than 2000 mg/kg for lead). These properties were identified for a time-critical removal action. Residents of eighteen of these twenty-one (86%) properties permitted EPA access to their property for remediation (EPA, 1998a, 1998b, 1999b).

In November 1998, following the Phase I and II field investigations, EPA conducted limited biomonitoring of residents at properties in the Elyria and Swansea neighborhoods with the highest arsenic or lead concentrations in soil. Blood lead, urinary arsenic, and hair arsenic analyses were performed on samples obtained from 15 volunteers who were living at six of the 21 residences identified for the removal action. Ages of participants ranged from 3 to 85 years. The majority (87%) of participants were 9 years of age or older. Blood lead concentrations were all less than 5 µg/dL. Arsenic was not detected in any urine sample (reporting limit > 20 µg/L) and was detected in only one hair sample at a concentration of 0.41 µg/g. EPA noted that while the biomedical data did not suggest elevated exposures to lead and arsenic significantly greater than normal, interpretation was limited due to the small number of participants. EPA proposed adding VBI-70 to the National Priorities List (NPL) on January 19, 1999, thus requiring the Agency for Toxic Substances and Disease Registry (ATSDR) to conduct a public health assessment (PHA) by January 2000.

In July 1999, EPA added the VBI-70 site on the NPL. In August 1999, EPA implemented a large, Phase III soil-sampling program as part of its remedial investigation of the site. Samples were obtained from 2,990 properties. Preliminary results indicated that 33 properties had average soil arsenic concentrations of 400 mg/kg or greater. Between 1998 and 2000 the EPA cleaned up the yards of these properties.

EPA completed the Final Baseline Human Health Risk Assessment for the VBI-70 Superfund Site on October 21, 2001. The results from the risk assessment indicated that some residential properties at the VBI-70 site had soil arsenic concentrations substantially higher than the expected natural levels. Properties with elevated concentrations of arsenic occur at widely scattered locations across the superfund site, with no discernable spatial pattern. The chemical form of the arsenic is predominantly arsenic trioxide. Soil lead concentrations were elevated in all neighborhoods of the site, but levels tended to be higher on the western side.

The ATSDR's draft PHA for the VBI-70 site was submitted for review on January 8, 2000 (ATSDR, 2000a). One of the preliminary recommendations from the PHA was to conduct a health study in the VBI-70 area. As a result of this recommendation, in May, 2001, ATSDR issued a non-competitive Program Announcement to the Colorado Department of Public Health and Environment (CDPHE) entitled "Soil-Pica, Soil-Ingestion and Health Outcome Investigation Site–Specific Health Activities" (Announcement 01108). The two-year award was granted to the CDPHE from ATSDR on September 30, 2001. CDPHE contracted with the University of Colorado Health Sciences Center (UCHSC) to conduct the soil-pica investigation at VBI-70. The contract with UCHSC became effective on October 15, 2001. The final PHA, prepared by ATSDR, was released to the public on August 12, 2003.

A Health Study Team was established to oversee the activities of the field staff and investigators. The team consisted of community members from Cole, Clayton and Swansea neighborhoods, CEASE (Clayton, Cole, Elyria, Swansea Environmental Coalition), local federal agencies (EPA and ATSDR Region VIII), Denver County Health Department, CDPHE, UCHSC, and Toxicology Associates. Meetings were held every two weeks during the field investigation (June 2002 through November 2002).

III. STUDY GOALS

The main goal of this study is to characterize soil contact activities and soil pica behavior among young children. The study surveyed soil contact activity of neighborhood children and measured concentrations of arsenic in their urine and lead in their blood. The primary goal of the survey for soil-contact activity was to describe the range of soil-contact activities reported by parents for children living in the VBI-70 neighborhoods and to determine the extent to which high-contact activities were reported. The primary goal of the analyses of biologic samples for arsenic and lead was to describe the ranges of concentrations of these metals in community children and to determine the extent to which children have elevated levels. Additionally, the correlation between soil contact, arsenic and lead concentrations, and concentrations of arsenic in urine and lead in blood was also evaluated.

IV. METHODS

IV.A. Study Design

This study characterized soil contact activities and soil pica behavior among young children in the VBI-70 neighborhoods in Denver, Colorado. A cross-sectional, door-to-door approach identified eligible children and assessed their soil exposures. Upon initial recruitment, participants were asked to provide a urine sample to be tested for arsenic and a fingerstick blood sample to be tested for lead. The soil contact data and arsenic and lead concentrations were correlated to help clarify the mass of soil ingestion when children play in or eat contaminated soil.

The in-person interviews and biologic sample collections were conducted from June 2002 through November 2002.

The reported soil-contact activities were linked to the specific play locations where they occurred and to the soil concentrations of arsenic and lead measured at these locations. By linking soil-contact activities of individual children with the concentrations of arsenic and lead measured in soils, we identified areas where children play that had not been sampled for soil analysis and offered to have these locations sampled. Results from sampling helped identify new areas of contamination that may need remediation. We also identified combinations of high soil-contact activity and high soil concentrations of arsenic and lead that were brought to the attention of parents in order to modify play activities to reduce exposures.

These data were used to determine whether the combination of data on soil contact and arsenic and lead concentrations were correlated with concentrations of arsenic in urine and lead in blood. Analyses with models of the relation between soil intake and biologic concentrations may also help clarify the mass of soil ingested when children play in contaminated soil.

Concurrent to the health study activities, EPA continued to test VBI-70 neighborhood soils and remediated yards as necessary. At the end of the study period, EPA had completed testing 3000 yards and remediated 51 of these yards. Three hundred eighty-four yards were identified as having elevated soil arsenic levels, 180 yards with elevated soil lead levels, and 95 yards with both elevated soil arsenic and lead levels (EPA, 2002a). EPA continues testing soils in these neighborhoods and plans to complete testing and remediation by September 2006 (personal communication).

Through the in-person interview, we recorded self-reported signs and symptoms of arsenic toxicity. Linking data on reported signs and symptoms with soil contact activity provided information that is considered important to community members and that clarified whether there is evidence of arsenic toxicity in neighborhood children. We realize that such analyses are of limited scientific value, particularly if they show no relation between soil exposure and signs and symptoms of disease. We included these data in analyses with soil exposure and biomonitoring data to determine whether there was evidence of acute or chronic arsenic toxicity in children and to address the concerns of residents over possible health risks to children and adults from exposure to contaminated soil.

IV.B. Eligibility Criteria

The VBI-70 study area is located in northern Denver, bounded on the west by the South Platte River, on the east by Colorado Boulevard, on the north by East 52nd Avenue, and on the south by Martin Luther King Boulevard.

Children were eligible for the study if they met the following criteria:

- the child was between 6 months and 6 years of age, and
- the child lived or attended school within the site boundaries for at least 14 days.

Any other children, seven years of age or older, or any adult in the household that wanted to be tested for arsenic or lead exposure could provide a sample for analysis. All test results were shared with participants; however, the results of these tests were not used in the final analysis of the study.

IV.C. FIELD PROCEDURES

C.1. Notification of Residents

Residents in the VBI-70 domain were informed of the project through published newsletters and notices at community functions. About two weeks before beginning interviews in a neighborhood study staff notified residents by mail that an interviewer would be contacting them to request their participation. Flyers were also left at each home two or three days before beginning interviews in a neighborhood.

C.2. Scheduling Interviews

Teams of two or three interviewers were assigned to conduct interviews in a group of blocks within a neighborhood. All study staff were easily identifiable, wearing specially designed study shirts. Additionally, each team had at least one bilingual team member. Study staff surveyed neighborhoods at all times of the day to increase the potential for making contact with all homes in the study area. The teams systematically contacted each residence on a street and then moved to the next street. If no one answered the door at a residence, an information sheet was left in the door. If someone was home, the interviewers introduced themselves, showed identification, and asked to speak with an adult member of the household. The interviewer provided a brief description of the survey, referring to the letter if appropriate. The adult was then asked if there were children aged 6 months to 6 years of age who lived in the household, or visited the home frequently. If there were no children meeting the eligibility criteria, the interviewer left and went to the next residence. If there were one or more eligible children, the adult was asked to identify the parents of the children to request that they participate in the study. If a parent was at home, he or she was asked to participate in the census, the soil-exposure survey, and to have his or her eligible child or children tested for arsenic and lead. If there were children in the household with different sets of parents, the interviewer identified one or both parents of each eligible child and made the appropriate requests. If a parent of an eligible child was not at home, the interviewer determined the best time to contact him or her and arranged to return at that time.

If a parent was not interested in participating at all, the interviewer documented the refusal and proceeded to the next residence. If a resident was willing to participate, then the interviewer proceeded with obtaining informed consent for the census.

C.3. Consent Procedures

To ensure protection of human subjects' rights, consent forms were reviewed and approved by the UCHSC internal review board (IRB). Consent forms explained the purpose of the study, the survey and specimen collection procedures, and rights of participants, including participation in some or all of the study activities. The parent or legal guardian was given a copy of the consent form to read or had the consent form read to them in English and/or Spanish, whichever the preferred language. Study staff answered questions raised and provided additional contact information to the participants should further questions arise.

IV.D. Study Instruments

D.1. Geographic Information System

Prior to conducting the census and interviews, a geographic information system (GIS) was prepared. The GIS depicted streets, residential and commercial lots, locations of parks and playgrounds, the location of homes with yards previously sampled by the EPA, census tracts, and aerial photographs with databases for street addresses of residents, demographic data for census blocks, and concentrations of arsenic and lead detected in residential yards.

The GIS was used to help plan interviewing logistics, and to orient interviewers with regard to the demographic characteristics of neighborhoods. We also used the GIS in the soil exposure survey to identify the places children play and to link soil contact activities with concentrations of arsenic and lead in soil. The GIS was also used to track the completion of the census of children and soil exposure interviews.

D.2. Census of Children

A census form was administered as part of the in-person interview. The census form recorded household mailing address, phone number, and type of dwelling (single family, multiple family, or trailer) along with data for each child that included last name, first name, middle initial, sex, age, and date of birth (Appendix B.1).

D.3. Soil-Exposure Survey

In the year prior to the beginning of the study, a unique survey questionnaire was designed for use in the VBI-70 site area. Questions were taken from several different surveys, suggested questions from ATSDR toxicologists, community toxicological advisors, the VBI-70 Working Group, and recommendations from an external panel of peer-reviewers. The questionnaire was piloted for one month. In July 2002, the Health Study Group, comprised of community members from Cole, Clayton, and Swansea neighborhoods, CEASE (Clayton, Cole, Elyria, Swansea Environmental Coalition), local federal agencies (EPA and ATSDR Region VIII), Denver County Health Department, CDPHE, UCHSC, and Toxicology Associates, requested the addition of dust/paint assessment questions to the survey to establish a possible link with lead exposures in the home. The questionnaire included questions about both indoor and outdoor play activities that may put the child in contact with soil, washing habits, and soil pica behavior. After each interview, the interviewer asked to look at the residence yard and visit other locations to estimate the percentage of exposed dirt in the play areas (Appendix B.2).

D.4. Signs and Symptoms Survey

During the in-person interview, a brief questionnaire was administered eliciting reports of symptoms consistent with acute and chronic arsenic toxicity in children. These signs and symptoms are widely recognized in medical texts and are discussed in the ATSDR Toxicological Profile (ATSDR, 2000). Additionally, these signs and symptoms were agreed upon after discussions with physicians, ATSDR, and the community coalition's scientific advisors. The survey asked about symptoms experienced by children in the past 2 months, and in the 3 days before collection of the urine sample (Appendix B.3).

D.5. Dust and Paint Assessment

Since dirt, dust, and paint containing lead are potentially important sources of lead exposure for young children we developed a series of standardized observations inside and outside the home to assess the conditions of windowsills, floors, and paint. After the interview, the interviewer asked the adult for permission to look at windowsills, paint, and floors in the main areas where the child played. The interviewer also explained the potential lead exposures from these sources and gave the adult educational material about keeping dirt, dust, and chipping paint at a minimum in the home (Appendix B.4).

D.6. Educational Materials

Following the completion of the soil exposure questionnaire, the field staff provided brochures, in Spanish and/or English, to explain the health effects of arsenic and lead, and provided information on how to reduce childhood exposures. The interviewer summarized the brochure with the participants, and answered any questions (Appendix C).

D.7. Consent Forms

As explained in the field procedures section above, prior to the administration of the questionnaire interviews and collection of any biological specimens, permission was requested of each parent or legal guardian of eligible children. Consent forms were reviewed in English and/or Spanish with study staff. Bilingual study staff answered any questions about the interview, study or consent process. Permission for initial and confirmatory specimen collection is covered in the consent form. All consent forms were reviewed and approved by the UCHSC IRB to ensure protection of the rights of human subject participants as part of the study protocol (Appendix D).

IV.E. SCREENING PROCEDURES

E.1. Collection and Analysis of Urine, Blood, and Hair Samples

After completing the census and soil exposure interviews, urine samples for arsenic and blood samples for lead were collected. All collection, storage, preparation, shipping, tracking, and analysis of the blood and urine samples were in accordance with EPA's 2002 document entitled "Sample Analysis and Quality Assurance Plan for Urinary Arsenic and Blood Lead Among Residents of VBI-70 Neighborhoods" (Appendix E). Participants were given the option of not providing biological specimens for testing.

We also explored the relationship between evidence in biologic samples for acute and chronic exposure by comparing urine arsenic concentrations to arsenic concentrations in hair in a small subset of participants. The sampling plan was designed to collect samples from three groups: (1) 20 subjects with the highest initial urine arsenic concentrations; (2) 20 subjects selected randomly from those who had detectable initial concentrations less than the background limit; and (3) 20 subjects who had the highest estimates of soil contact activity based on data from the in-person interview. For these subjects, urine samples were re-collected and analyzed for total inorganic arsenic concentrations, as described previously.

E.2. Verifying and Reporting Results

It took approximately seven working days to receive results from blood lead and urine arsenic analyses. Negative results were reported by mail to adult participants, parents or legal guardians of children. Results higher than lead and total inorganic arsenic cut-off levels were shared with parents or legal guardians by telephone. Additional specimens were collected for confirmatory tests. Venipuncture blood samples were collected to test for blood lead and an additional urine specimen to test for arsenic.

E.2.a. Urine Arsenic Concentrations

An action level of ≥ 30 μg/L was selected for total urinary arsenic. This action level was decided upon by consensus of the Health Study Team, Drs. James Ruttenber and Michael Kosnett, toxicologists at Syracuse Research, EPA, and the CPDHE. This level was determined based upon expected concentrations of urinary arsenic resulting from dietary sources. As reported in the literature, daily consumption of arsenic from dietary sources averages approximately 40 μg/day (ATSDR, 2000). Therefore, the decision to report initial total arsenic concentrations less than 40 μg/L was made assuming that these levels would be below concentrations expected when dietary intake of food contained arsenic. If arsenic was detected in concentrations at or above the pre-determined level of 30 μg/L, we notified by telephone the adult participants or the parents or guardians of the child participants. They were told that the results of their analyses were not normal and collection of another sample for a repeat analysis was recommended. A repeat urine sample for arsenic was collected in the same manner as described above.

If urine arsenic concentrations were above the established background level on the repeat analysis, the adult participants and the parents or guardians of child participants were notified by telephone. We offered to visit the home of the child to discuss the health consequences of the elevated urine concentration as well as talking with the child's physician. We also offered to arrange for the EPA to perform an evaluation of the child's home. This evaluation included a review of soil sample data and possibly the collection of indoor dust samples and additional soil samples.

E.2.b. Blood Lead Concentrations

An action level of ≥ 10 µg/dL of lead in blood was selected based on Centers for Disease Control and Prevention (CDC) recommendations. If an initial blood lead concentration was equal to or above 10 µg/dL, project staff requested that another blood sample be collected by venipuncture. Study staff made appointments for the blood collection and trained medical personnel in local clinics collected the repeated blood samples.

If the blood lead concentration was greater than or equal to 10 µg/dL in the repeat sample, the parents of the child were notified and a staff member offered to consult with the child's physician. A blood lead concentration greater than or equal to10 µg/dL in children 18 years or younger is a reportable environmental condition in the State of Colorado. We complied with State law by notifying CDPHE of the case within 30 days. The report to CDPHE included the person's name, age, sex, address, county, phone number, and the person's physician's name and address. The CDPHE then referred the case to the County of Denver. The Denver County Health Department performed a household survey investigation to identify possible exposure routes and recommended methods to reduce exposure.

IV.F. Community Informational Meetings

We conducted a series of community meetings to provide additional information to residents about soil and lead arsenic concentrations in neighborhood soils, plans for remediation activities, and possible health risks from past, current, and future exposures. The meetings were scheduled in each neighborhood following the completion of the administration of the soil-exposure survey. Health professionals were present to answer questions about the health effects of arsenic and lead, and to consult with residents who were concerned that they or their children may have acute or chronic arsenic toxicity. Residents were also encouraged to implement exposure reduction practices and were provided information on whom they could contact about health concerns in the future.

V. DATA MANAGEMENT AND DESCRIPTIVE ANALYSES

V.A. Data Management

Data from the census of children, soil exposure interviews, signs and symptoms survey, and dust and paint assessment was collected on hard-copy interview forms that were designed for rapid entry into an electronic database. At the end of each 12 hour shift, each interviewer reviewed the written responses and made sure they were complete. Interviewers also recorded appointments that had been made for urine and blood sample collection.

Project staff entered the data from the census of children and soil exposure survey. The electronic census and interview data were edited by comparing them with the original hard-copy data and, if necessary, appropriate corrections were made. Interview forms with missing data were returned to the interviewer, who made corrections and re-contacted the interviewee if necessary.

All data were maintained in locked cabinets on password protected computer systems in locked offices. The database was translated from Microsoft Access to SAS and combined with data from the GIS data. All analyses were performed using Version 8.2 of the Statistical Analysis System (SAS) for Windows.

V.B. Statistical Plan

To address the study goals, descriptive statistical analyses were conducted. In addition to the descriptive analysis, univariate analyses were conducted to determine if elevations in blood lead or urine arsenic concentration could be explained by soil-contact activities or other behavioral activities. Statistical significance was evaluated at the 95% confidence level. Both Wilcoxon Rank-Sum and Kruskal-Wallis tests were performed to evaluate statistical significance among the descriptive variables and p-values less than or equal to 0.05 were considered statistically significant.

Given the descriptive nature of the study and the defined geographic boundaries of the neighborhoods of interest, power calculations were not considered *a priori* in the recruitment phase. A review of 2000 Census data indicated a large number of children under the age of 6 (approximately 2700) residing within the VBI-70 neighborhood.

VI. RESULTS

Interviewers identified 4,389 houses or apartments in the study area, and made contact with an adult resident in 3,978 (90.6%) of these residences. Of the 411 households interviewers were unable to contact, 353 (85.9%) had no one at home each of the four times an interviewer visited . Of the households contacted, 1290 reported having one or more children in the eligible age range (6 months to less than 7 years of age); of these households, 772 (59.8%) had one or more eligible child participate in the study. There were 1,072 eligible children in these 772 households. Of the 518 eligible households that did not participate, 385 (74.3%) refused participation and 133 (25.7%) were unable to arrange a home visit during the study period (Table 1a).

While they were too old to be included in the eligible study population, there were 638 children and adults who submitted urine, blood, or hair samples for analysis because they or their parents were concerned about exposure to arsenic or lead.

The mean age of eligible subjects was 43.8 months, and the mean residence length was 23.6 months. The sexes were similarly represented among the eligible study participants (52% male, 48% female). Approximately 77% of the eligible children were Hispanic, 8% Black, and 3% White. Race and ethnicity was collected during the interview and was self-reported. Participants self-identified race and ethnicity from the following categories: Anglo, Hispanic, Black, Asian, or American Indian (Appendix B.2). Of 1072 eligible participants, 848 (79.1%) submitted a urine sample and 977 (91.1%) submitted a blood sample. Parents completed interviews for 988 (92.2%) of these children. The majority of interviewed subjects self-identified as Hispanic, and most interviews were conducted in Spanish (63%) (Table 1b). Eligible subjects without interview data were similar to eligible subjects whose parents completed interviews with respect to gender and age (Table 1c).

Of the 1072 eligible participants 929 children had both interview and specimen collection. Of the 988 who were interviewed, 763 (77%) agreed to both the blood and urine specimen collection (Table 2). Initial blood lead levels were elevated for approximate 7% of the non-interviewed and 5.5% of the interviewed participants. However, there was little difference between the interviewed and non-interviewed groups upon confirmatory testing (Table 1c).

Of the 983 children with interview data, 713 (72.5%) reported to have played with dirt one time a week or more for an average of 7 hours per week. Approximately 50% of the 983 children reported eating or drinking outside (50.4%) or playing with objects (48.7%) for two and four hours per week, respectively. Approximately 95% of eligible participants reported playing outside on average twenty hours per week; the median number of hours per week spent playing outdoors was 17.0 ; and there were 82 children (9.1%) who were reported to have eaten dirt in the two weeks preceding the interview (Table 3).

Of 988 child subjects, 204 (20.7%) were reported to have ever eaten dirt, and most ate quantities less than the amount contained in a bottle cap. Seven percent of children ate vegetables grown in neighborhood gardens and only about 10% reported less than usual soil contact in past two weeks (Table 4).

The majority of children washed their faces before going to bed and after playing (Table 5). About half of the area of subjects' yards was reported to be exposed dirt. For personal hygiene activities, the median frequencies per day were 2 for face washing, putting fingers in mouth, and putting objects in mouth. On average, parents reported washing children's hands five times per day (Table 5).

Concentrations of total arsenic measured in urine samples from subjects ranged between 1.0 and 92 μg/L, with a mean of 5.6 μg/L. Eight initial samples had concentrations $\geq$ 30 μg/L total arsenic. Upon confirmatory testing, however, no samples tested greater than 10 μg/L. Compared with older subjects, those one year of age or younger had lower concentrations of total urinary arsenic. Concentrations for males and females were similar, and concentrations were fairly similar between categories of race and ethnicity (Table 6).

Arsenic concentrations in hair were tested in a subsample of eligible participants. Included in this cohort were the eight children with initial elevated total urine arsenic concentrations. The protocol proposed resampling a total of 20 participants. However, given only eight specimens had initially elevated test results the additional 12 participants were selected from the initial specimens with next highest total urine arsenic concentrations. For comparative purposes additional hair samples were collected from those participants with the highest soil arsenic concentrations and then from a random selection of remaining participants without initially elevated total urine arsenic levels. Initial total arsenic concentrations ranged between 0.02 µg/g and 0.52 µg/g, with a mean of 0.1 µg/g. Arsenic concentrations in hair were similar for males and females, and across age groups. Forty (of 46) hair samples were collected from Hispanic children (Table 7). There was no correlation between initial urine concentrations and hair concentrations ($r^2 = 0.0208$).

Concentrations of lead in finger-prick blood samples from subjects ranged between 0.9 and 76 µg/dL, with a mean of 4.6 µg/dL. Compared with other subjects, those one year old or younger and six years old had lower concentrations. Mean concentrations for males were statistically significantly higher than females. Concentrations were fairly similar between categories of race and ethnicity though concentrations were higher among Anglos (6.5 vs. 4.2-4.5) although not statistically significant. On re-analysis of samples from 55 children who had concentrations of 10 µg/dL or higher, concentrations in venous blood were elevated in 23 subjects. The blood lead concentrations in the confirmatory samples were generally lower than the initial concentrations. Of the 23 subjects with consistently elevated concentrations, 3 (13%) were evaluated for possible exposure sources. Of this group, sources were identified and exposure intervention was implemented for all. One subject was administered chelation treatment.

When stratified by housing characteristics, blood lead concentrations increased with levels of visible dust on floors, with levels of visible dust on windowsills, with levels of the general degree of visible paint chipping and peeling, with the degree of chipping and peeling of paint around windowsills, on other painted wood surfaces, and on exterior painted surfaces (Table 9).

About 3% of children were reported by parents to have been diagnosed with anemia. The complaint of stomach pains and cramps was the most frequently reported sign or symptom for both three and sixty days before the interview (Table 10a). A comparison of urine arsenic and blood lead concentrations with parent-reported signs and symptoms indicates no relation between most of the variables and either arsenic or lead concentrations (Table 10b). Diarrhea was the only symptom in the 60 days prior to interview that was reported statistically more often between the two groups for children with elevated blood lead levels. A p-value was calculated using the Fisher Exact Chi-square test for significance.

Univariate regression models to evaluate the relationship between soil-contact activities, personal hygiene variables, and urine arsenic and blood lead concentrations show statistically significant negative correlations between urine arsenic concentrations and the percent time face washed prior to playing, the percent time hands and faces are washed before bed, and a statistically significant positive correlation with length of residence in current home (Table 11). A significant relationship between blood lead levels and residential length in months ($p<0.001$)

and mean residential soil lead concentration was observed (p=0.02) (Table 12). Similarly, a significant relationship between hair arsenic concentrations and residential length in months (p=0.05) was observed (Table 13). However, the r^2 values for these correlations are extremely small, suggesting that the noted variables are not important predictors of urine arsenic or blood lead concentrations. Univariate analyses were conducted using results from initial blood lead and urine arsenic sample results. The analyses were limited to these results given too few elevated confirmatory results. While using confirmed elevated results would have been preferable, the initial results were the only data available to provide some information about the relationship between blood lead and urine arsenic and behavioral characteristics in this study population.

VII. DISCUSSION

In the community census, 772 of 1290 (59.8%) eligible households participated with 1072 eligible subjects identified. Of these, 988 (92.2%) completed interviews, 848 (79.1%) submitted urine samples, and 977 (91.1%) submitted blood samples. Among those eligible participants identified, the participation rate was similar, if not greater, than the participation rate for households in other studies. For example, Hwang et al. (1997) reported a participation rate of 85.8%. However, in a similar study conducted in a neighborhood adjacent to the VBI-70 study area (Gottlieb et al., 1993), 42.3% of eligible subjects completed interviews, 32.6% submitted urine samples, and 40.0% submitted blood samples.

Eligible subjects played outside a median of 17 hours per week, and over half the time was spent in contact with soil. The majority of children did not play with objects or pets, and did not have pacifiers or thumbs in their mouths when playing outdoors. Eligible subjects played with dirt a median of 2.5 hours per week.

We have been unable to find published, population-based studies of soil-contact activities of children. Descriptive studies of soil pica are also rare and are difficult to make comparisons with because most have not produced estimates of the frequency of soil ingested per unit time, or the quantities of soil ingested per unit time. Over the past decade, most research on soil intake has focused on quantitative estimates for use in risk assessments (U.S. Environmental Protection Agency, 2002a). These quantitative estimates have been made with studies of metal tracers for soil and dust in feces of children—studies that estimate both intentional and unintentional ingestion of both soil and household dust.

In our study, 20.7% of children were reported by parents to have ever eaten dirt, and 9.1% were reported to have eaten dirt in the past two weeks. In a summary of an observational study of Jamaican children aged 0.3—7.6 years conducted by Wong (1988), Calibrese & Stanek (1993) reported that 4 of 15 children (26.7%) had evidence of some soil ingestion in each of the four once-a-month samples, and that 52.8% of all 87 samples showed evidence of some soil intake. In this study, 5 of 24 children (20.8%) ingested more than 1g of soil a day.

In the two weeks before the interview, children were reported to have played about half as much indoors as outdoors, and half of all subjects had yards with 50% exposed dirt. Over half of eligible children were reported to have washed hands after playing and before going to bed.

VII.A. Arsenic Exposures

The soil concentrations of arsenic in the yards of eligible subjects ranged between 5.5 ppm and 474.2 ppm, with mean and geometric mean concentrations of 26.8 ppm and 2.57 ppm, respectively. Concentrations of non-dietary arsenic in urine for our study subjects are similar to those reported for other studies of subjects with similar soil arsenic concentrations. Ranft et al. (2003) studied older adults in a Slovakian population living near a coal-fired power plant, and measured median, mean and geometric mean concentrations of 6.04, 7.46 and 6.02 µg/dL, respectively. The soil arsenic concentrations in this area were within the range of background for Europe (2-20 ppm).

The urine arsenic concentrations for eligible subjects were lower than those measured in subjects in other investigations where soil concentrations of arsenic were higher than that measured in this study area. Hwang et al. (1997) measured non-dietary arsenic concentrations in urine samples from 289 children younger than 72 months who lived near a former copper smelter and related these to concentrations of arsenic measured in soil from the yards where subjects lived. The geometric means of grouped soil samples from areas near the smelter ranged between 63 and 377, and between 66 and 119 ppm from areas further away from the site. Geometric mean concentrations of non-dietary arsenic ranged between 9.1, 8.6, and 7.2 for the close, intermediate, and remote areas, respectively.

Urine samples were re-collected and re-analyzed from eight subjects who had initial arsenic concentrations of 30 µg/L or greater. On re-analysis, the concentrations were all below this level–suggesting either that dietary sources were likely to have been responsible or that environmental exposures to arsenic were not consistently high. Based on data presented below, this latter explanation is unlikely.

Concentrations of arsenic in hair were not correlated with initial concentrations that were measured in urine, and not correlated with concentrations of arsenic in soil samples from household yards. Most hair arsenic concentrations were lower than 0.02 µg/g—the upper range for a group of child and adult subjects who had housing-area soil arsenic concentrations that were 50 ppm or less (Gebel et al., 1998). These authors also noted that arsenic concentrations in hair were about three times higher in the region chosen to represent background exposure as compared with an area of known elevations in soil arsenic concentrations.

No meaningful relationships between concentrations of arsenic in urine and different soil-contact behaviors were found; nor were relationships for exposure metrics that incorporated estimates of soil contact time with soil concentrations in play areas, or the soil concentrations in the yards of residences discovered. Gebel et al. (1998) found a weak ($r^2 = 0.032$) but statistically significant correlation between concentrations of nondietary arsenic and soil samples from the housing areas of subjects in a multivariate model. Hinwood et al. (2003) found similar results for concentrations of arsenic in hair, with a significantly elevated regression coefficient in a multivariate model, and a correlation coefficient of 0.16.

VII.B. Lead Exposures

The soil concentrations of lead in the yards of eligible subjects ranged between 26.0 ppm and 903.7 ppm, with mean and geometric mean concentrations of 217.6 ppm and 5.22 ppm, respectively. The distribution of lead concentrations in finger-prick samples is similar to those reported in other studies. In a summary of lead concentrations in venous blood samples collected in the third National Health and Nutrition Examination survey (NHANES III), conducted between 1991 and 1994 with 2,392 children aged 1-5 years (Centers for Disease Control and Prevention [CDC], 1997), the weighted geometric mean for children aged one to five years was 2.7 μg/dL. In the CDC study, the geometric mean blood lead levels was highest for non-Hispanic blacks (4.3 μg/dL), next highest for Mexican Americans (3.1 μg/dL), and lowest for non-Hispanic whites (2.3 μg/dL). There was also an inverse relationship between income and blood lead levels for subjects in this study. The geometric mean for blood lead concentrations among children participating in this investigation was higher than the geometric mean reported nationally. This finding has promoted further educational and blood lead screening efforts in the VBI-70 neighborhood.

In a more recent study with data from NHANES 1999-2000 for children aged one to five years (Meyer, 2003), the geometric mean for venous blood lead levels was 2.23 μg/dL, with 25th and 75th percentiles of 1.40 and 3.30, respectively. The differences in blood lead concentrations between the VBI-70 study population and analyses based on a sample of the U.S. population may be due, in part, to the fact that the NHANES blood lead levels were measured in venous blood samples, and our measurements were made with finger-prick samples. It is also possible that the geometric mean blood lead levels in our population are higher than those for U.S. children in general because of the environmental exposures and factors associated with race, ethnicity, socioeconomic status, and location.

In the NHANES III study with samples collected between 1991 and 1994 (CDC, 1997), 4.4% of children between the ages of 1-5 years had venous blood lead levels ≥10 μg/dL. Bernard & McGeehin (2003), with NHANES III data for 1998-1994, reported that 6.3% of subjects had blood lead levels ≥10 μg/dL, and 25.6% had blood lead levels ≥5 μg/dL. These researchers reported associations between elevated blood lead levels and race, ethnicity, and socioeconomic status that are similar to those noted above. In the VBI-70 study population, 5.6% of eligible subjects had finger-prick blood lead levels ≥10 μg/dL, and 25% had blood lead levels ≥5.5 μg/dL—distributions similar to those noted in the other studies.

For eligible subjects in the VBI-70 study population, males had significantly higher blood lead levels than females—a finding similar to that for all subjects aged 1 year and older in the 1999-2000 NHANES III (Meyer, 2003).

The mean blood lead levels increased with levels of dirt and dust on windowsills and floors and with evidence of flaking or chipping of painted surfaces, while urine arsenic concentrations were not influenced by these variables. Blood lead levels were also higher for subjects who had soil lead concentrations higher than the median for all subjects, as compared with those who had lower soil concentrations. Univariate regression models did not, however, identify any important association between soil exposure or personal hygiene variables and blood lead levels. Multivariate models that accounted for both duration of soil exposure and soil concentrations of lead in play areas also did not show relations between soil exposure and blood lead levels. Our findings are in contradiction to those of Mielke, et. al. (1997), who found correlations between median soil and blood lead concentrations for census tracts in an ecologic analysis.

VII.C. Strengths

The Kids at Play health study presented a unique opportunity to provide important biomedical screening services to an underserved community. Given that the study design included a neighborhood census, approximately 90% of the households in the neighborhood were contacted. As such, almost 1,300 households were offered blood lead and urine arsenic screening, reaching children who may have otherwise not had the opportunity to be tested. In addition to providing biological tests, medical services were provided through collaborations with state and local public health services.

Coordinated efforts with EPA provided testing of soil concentrations for lead and arsenic and offered remediation of those properties with elevated levels of lead, arsenic, or both. During the health study, soil samples were collected for more than 500 properties (approximately 50%) in the neighborhood. Both the biologic and property samples collected provide a baseline for future medical monitoring.

Educational materials and messages were designed specifically for residents of the VBI-70 neighborhood. All materials were provided in both English and Spanish. Members of the study staff were bilingual, facilitating communication with neighborhood residents in the language in which they felt most comfortable.

The health study was additionally strengthened by a dedicated group of staff members. The study staff worked twelve hours shifts. Teams worked seven days a week during the study period.

Age of home data were also available for analysis. This was important in evaluating paint as a source for lead exposure. The study also is unique for collecting and analyzing all-play activity locations.

Finally, the ability to conduct the study and to get such community support and acceptance was the result of coordinated effort and close involvement with the community coalition. Similarly, cooperation with state, local, and federal agencies made the health study possible.

VII.D. Limitations

As with most scientific studies, the results of this health investigation may have been influenced by some limitations. By design all information collected via the survey instrument was self-reported. Similarly, signs and symptoms of arsenic exposure and other reasons for experiencing these signs and symptoms, such as having a cold or food poisoning, may have been difficult to differentiate.

Collection of information pertaining to quantity of soil intake, characterization of soil pica activities, and characterization of play activities were all self-reported measures, too. The study design did not allow for means of validating any of these activities.

The ability to recruit all eligible participants may have been influenced by the fact that the study occurred during the summer. While there was the advantage of finding more eligible children at home, families may have been away from the neighborhood because of summertime travel plans. Similarly, it was a very hot summer and, therefore, eligible children may not have been participating in outdoor activities as often as they would have had the summer temperature been more comfortable. In fact, the study period occurred during one of the hottest summers. According to the National Weather Service, the temperature reached 100 degrees Fahrenheit in August 2002 and the average daily high temperature was 91.5 degrees in July 2002, making July the ninth warmest July on record.

VIII. CONCLUSIONS

The concentrations of arsenic in urine samples from eligible subjects are similar to those reported in the literature for low levels of environmental exposure and are substantially lower than those reported for children exposed to high concentrations of arsenic in soil and drinking water. The urine arsenic concentrations were not related to soil arsenic concentrations. These data suggest that the health risks from arsenic exposure associated with contamination from past metal smelting activities in the VBI-70 neighborhood are small.

The geometric mean blood lead levels in eligible subjects are slightly higher than those from the most recent CDC survey, but the percentage of subjects with blood lead levels ≥ 5 µg/dL is similar to what has been reported for the general population of U.S. children. The blood lead levels were not found to be correlated to outdoor soil exposures or high soil-contact activities. A number of variables indicative of exposure to indoor dust and paint-chip exposure were related to blood lead levels. Our results suggest that exposure to contaminated soil during normal outdoor play activities has not resulted in lead exposures that are unusually high in comparison with U.S. children. Our data suggest, however, that direct soil ingestion may have resulted in elevated blood lead levels in a few children.

IX. RECOMMENDATIONS

Although it is not clear that exposure to contaminated soil has resulted in elevated exposures to either arsenic or lead, the high percentage of children reported by parents to have ingested soil suggests that efforts to notify parents of risks associated with soil pica behavior may reduce exposures to these agents.

The identification of 23 children with confirmed elevations of blood lead levels indicates the value of population-based education and screening in communities at high risk for lead exposure.

Therefore, the following are recommendations for follow-up activities by an appropriate local agency:

- Ongoing education to neighborhood families about the lead and arsenic ingestion and ways to minimize risk;
- Continue screening for lead exposure among neighborhood children; and
- Continue remediation of neighborhood yards, as necessary.

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APPENDIX A -- TABLES

Table 1-a. Descriptive Demographic Data

Households identified and contacted	N	Percent
Households in study area	4,389	
Households contacted	3,978	90.6
Households not contacted	411	9.4

Household recruitment	N	Percent
Households with no eligible children	2,688	
Households with eligible children	1,290	
Eligible households participating	772	59.8
Eligible households not participation	518	40.2
Eligible children	1,072	

Reasons for not contacting households		Percent
Dog(s) prevented access	44	10.7
Locked gate	14	3.4
Not at home*	353	85.9
Households not contacted	411	

Reasons for not participating		Percent
Unable to schedule interview	133	25.7
Refused to participate	385	74.3
Non-participating households	518	

*Households were contacted, on average, four times at different hours of the day and days of the week.

Table 1-b. Demographic and Sample Collection Data for Eligible Subjects

	Eligible subjects	
	N = 1072	
	n	Mean
Age (months)	1063	43.8
Residence length (months)	988	23.6
	n	(%)
Sex		
Male	556	51.9
Female	515	48.0
Unknown	1	0.1
Race and ethnicity		
Anglo	36	3.4
Hispanic	830	77.4
Black	86	8.0
Asian	1	0.1
American Indian	3	0.3
Multiple	31	2.9
Unknown	85	7.9
Interview Completed	988	92.2
Language of interview		
English	367	37.2
Spanish	621	62.9
Samples collected		
Urine	848	79.1
Blood	977	91.1
Hair	46	4.3

Table 1-c. Demographic and Descriptive Data for Eligible Subjects by Interview Status

	Not Interviewed N = 84			Interviewed N = 988		
Variable	n	Mean	Standard Deviation	n	Mean	Standard Deviation
Age (months)	75	43.1	24.2	988	43.9	22.4
Sex	n	%		n	%	
Male	42	50.0		514	52.0	
Female	41	48.8		474	48.0	
Unknown	1	1.2		0	0.0	
Samples collected						
Blood sample collected	72	85.7		905	91.6	
Initial blood lead sample elevated	5	6.9		50	5.5	
Confirmatory blood sample elevated	1	1.4		22	2.4	
Urine sample collected	61	72.6		787	90.0	
Initial urine arsenic sample elevated	0	0.0		8	1.0	
Hair sample collected	3	4.2		43	4.8	

Table 2. Sample Collection for Participating Eligible Children by Interview Status

Sample collection	Not Interviewed		Interviewed	
	N	%	N	%
No sample collected	9	10.7	59	6.0
Urine sample only	3	3.6	24	2.4
Blood sample only	14	16.7	142	14.4
Both blood and urine sample	58	69.1	763	77.2
Total	84		988	

Table 3. Time Spent by Eligible Subjects in Soil-contact Activities in Two Weeks Before Interview

	All responses	Activity reported	Time (hours/week)				
	N	N (%)	Mean	Standard Deviation	Median	Percentile	
						25th	75th
All soil contact activities	983		17.4	22.0	9.0	2.5	24.0
Playing with dirt	983	713 (72.5)	7.4	11.1	2.5	0.0	10.0
Eating or drinking outside	982	495 (50.4)	2.3	4.7	0.2	0.0	2.0
Playing with objects	983	497 (48.7)	4.1	8.1	0.0	0.0	5.0
Playing with pet	983	167 (17.0)	1.3	5.0	0.0	0.0	0.0
Thumb/pacifier sucking	982	323 (32.9)	1.8	6.0	0.0	0.0	0.6
Total time playing outside	983	930 (94.6)	20.0	15.6	17.0	7.5	28.0
Eating dirt (times/day)	899	82 (9.1)	0.2	1.0	0.0	0.0	0.0

Table 4. Soil Exposure and Pica Behavior for Eligible Subjects

	N	Percent
Has child ever eaten dirt?		
Yes	204	20.7
No	784	79.7
Amount of dirt last eaten		
≤ ½ eraser	21	10.3
> ½ eraser, ≤1 eraser	77	37.7
> 1 eraser, ≤ 1 bottle-cap	79	38.7
> 1 bottle-cap	23	11.3
Does child eat vegetables grown in neighborhood garden?	69	7.0
Was soil contact in past two weeks different than usual?		
Same level	696	70.5
Less contact	100	10.1
More contact	192	19.4

Table 5. Personal Hygiene Variables (N= 988)

Variable	Mean	Standard Deviation	Median	Percentile 25th	Percentile 75th
Time played inside (hours/day)	5.5	3.8	5.0	3.0	8.0
Percent of time:					
Face washed before bed	69.2	39.2	100	50.0	100
Face washed before eating	35.1	39.0	17.5	0.0	70.0
Face washed after playing	64.4	39.6	80.0	30.0	100
Hands washed before bed	72.0	37.3	100	50.0	100
Hands washed before eating	81.9	26.2	100	70.0	100
Hands washed after playing	79.4	52.4	100	50.0	100
Number of times per day:					
Face washed	2.8	2.1	2.0	1.0	3.5
Hands washed	4.9	3.5	4.0	3.0	5.5
Objects in mouth per day	8.7	33.6	2.0	0.0	6.0
Fingers placed in mouth	7.6	24.7	2.0	0.0	7.5
Percent of yard that is exposed dirt outside	45.6	36.1	50.0	10.0	80.0

Table 6. Total Urine Arsenic Concentrations (μg/L) for Eligible Subjects

							Percentile		
Variable	N	Mean	Standard Deviation	Geometric Mean	Geometric Standard Deviation	Median	25th	75th	p*
All subjects	848	5.6	6.3	3.8	2.4	4.0	2.0	7.0	
Sex									0.580
Male	453	5.7	6.3	3.8	2.5	3.9	1.9	7.1	
Female	395	5.6	6.3	3.8	2.4	4.2	2.0	6.9	
Age in years									<0.0001
< 1	51	3.0	5.9	1.8	2.3	1.0	1.0	2.7	
1	124	3.1	3.9	2.1	2.2	1.7	1.0	3.5	
2	131	5.5	5.5	3.6	2.6	3.8	1.5	7.7	
3	142	6.6	7.0	4.5	2.4	4.2	2.8	7.7	
4	118	7.0	8.9	5.3	2.0	5.4	3.4	8.2	
5	150	5.3	3.4	4.4	2.0	4.7	3.0	6.9	
6	132	7.2	7.2	5.0	2.4	5.2	2.9	9.2	
Race and ethnicity									0.059
Anglo	21	5.2	3.3	4.1	2.1	5.2	2.4	7.2	
Hispanic	692	5.6	6.5	3.7	2.5	3.9	1.8	7.0	
Black	53	7.4	7.4	5.2	2.3	5.2	2.9	7.9	
Other	20	4.2	3.6	3.0	2.4	3.4	1.0	5.7	
Subjects with elevated urine arsenic concentrations	N	Percent							
Initial sample ≥30 μg/L	8	0.94							
Confirmatory sample ≥10 μg/L	0	0							

*Wilcoxon Rank-Sum

Table 7. Hair Arsenic Concentrations (μg/g) for Eligible Subjects

							Percentile		
Variable	N	Mean	Standard Deviation	Geometric Mean	Geometric Standard Deviation	Median	25th	75th	p
All subjects	46	0.09	0.08	0.07	2.08	0.07	0.04	0.11	
Sex									0.071*
Male	29	0.10	0.10	0.08	2.15	0.07	0.04	0.13	
Female	17	0.06	0.04	0.05	1.83	0.05	0.03	0.08	
Age in years									0.115†
< 1	4	0.09	0.03	0.09	1.35	0.09	0.07	0.12	
1	9	0.11	0.16	0.07	2.49	0.06	0.03	0.10	
2	8	0.11	0.05	0.10	1.83	0.11	0.07	0.17	
3	8	0.09	0.08	0.07	2.14	0.06	0.04	0.12	
4	7	0.08	0.06	0.06	1.99	0.04	0.04	0.13	
5	4	0.08	0.05	0.06	2.29	0.08	0.04	0.12	
6	6	0.03	0.01	0.03	1.47	0.04	0.02	0.04	
Race and ethnicity									0.196†
Anglo	1	0.18		0.18					
Hispanic	40	0.08	0.09	0.06	2.09	0.06	0.04	0.11	
Black	2	0.11	0.06	0.10	1.71	0.11	0.07	0.15	

*Wilcoxon Rank-Sum
†Kruskal-Wallis Test

Table 8. Blood Lead Concentrations (µg/dL) in Finger-prick Samples from Eligible Children

							Percentile		
Variable	N	Mean	Standard Deviation	Geometric Mean	Geometric Standard Deviation	Median	25th	75th	p*
All subjects	977	4.6	4.0	3.7	1.9	3.7	2.4	5.5	
Sex									<0.001
Male	510	4.7	3.2	3.9	1.9	4.0	2.7	5.8	
Female	467	4.4	4.7	3.5	1.9	3.4	2.4	5.2	
Age in years									<0.0001
< 1	74	3.8	3.1	3.1	1.9	2.9	2.1	4.7	
1	168	5.4	6.5	4.1	2.0	4.1	2.6	6.6	
2	161	5.3	4.2	4.2	2.0	4.0	2.8	6.8	
3	154	4.3	3.3	3.5	1.9	3.8	2.4	5.2	
4	128	4.6	2.8	3.9	1.9	4.0	2.8	6.0	
5	152	4.1	2.3	3.4	1.9	3.6	2.3	5.3	
6	140	3.8	2.8	3.2	1.7	3.3	2.4	4.5	
Race and ethnicity**									0.348
Anglo	30	6.5	13.5	3.6	2.4	3.1	2.2	5.0	
Hispanic	775	4.5	3.3	3.7	1.9	3.8	2.6	5.6	
Black	67	4.2	2.6	3.5	1.8	3.8	2.3	5.0	
Other	32	4.4	4.4	3.3	2.0	3.5	2.4	4.5	
Subjects with blood lead concentrations ≥10 µg/dL	N	Percent							
Initial sample	55	5.6							
Confirmatory sample	23	2.4							

* Wilcoxon Rank-Sum

** N=904, 73 missing race and ethnicity

Table 9. Blood Lead Concentrations by Housing Characteristics for Eligible Participants

			Blood lead (µg/dL)			
	N	(%)	Mean	Standard Deviation	p*	
Dirt or dust on windowsills**					<0.001	
None	268	32.3	4.2	5.2		
Some	481	58.0	4.7	3.0		
Lots	81	10.0	6.1	4.6		
Dirt or dust on floors**					<.001	
None	488	58.7	4.3	4.2		
Some	298	35.9	5.0	3.3		
Lots	45	5.4	6.6	5.6		
General condition of interior paint**					<0.001	
No paint	14	1.8	3.2	2.7		
Intact	534	68.4	4.4	4.2		
Fair	205	26.3	5.2	3.9		
Poor	28	3.6	6.8	3.0		
Condition of paint on window frames**					<0.001	
No paint	46	5.5	3.4	2.0		
Intact	418	50.2	4.4	4.6		
Fair	274	32.9	4.7	3.5		
Poor	94	11.3	5.9	3.3		
Condition of interior painted wood (not window frames)**					<0.01	
No paint	88	10.6	4.9	3.4		
Intact	466	56.1	4.3	4.3		
Fair	230	27.7	5.1	3.7		
Poor	46	5.5	5.4	3.0		
Condition of outside paint**					<0.01	
No paint	168	20.2	4.4	2.9		
Intact	320	38.4	4.2	2.8		
Fair	260	31.2	5.2	5.8		
Poor	85	10.2	5.3	3.0		
Year house was built**						
≤ 1894	466	47.2				
> 1894 and ≤ 1926	168	17.0				
> 1926 and ≤ 1947	162	16.4				
> 1947	192	19.43				

*Kruskal-Wallis test for significance
**Questions added to interview in July

Table 10-a. Parent-reported Signs and Symptoms (N=988)

Variable	N	(%)
Ever diagnosed with anemia	29	2.9
Reported 3 Days Prior to Interview		
Diarrhea	84	8.5
Headache	59	6.0
Nausea	59	6.0
Stomach Pain or Cramp	131	13.2
Red Skin	106	10.7
Vomiting	66	6.7
Reported 60 Days Prior to Interview		
Diarrhea	211	21.4
Headache	147	15.0
Nausea	150	15.2
Stomach Pain or Cramp	267	27.1
Red Skin	182	18.4
Vomiting	190	19.3

Table 10-b. Parent-reported Signs and Symptoms Stratified by Blood Lead (N=905)*

	Elevated Blood Lead (N=50)		Normal Blood Lead (N=855)		p**
Variable	n	(%)	n	(%)	
Anemia	1	2.0	27	3.2	1.00
Symptoms Reported 3 Days Prior to Interview					
Diarrhea	5	10.0	69	8.1	0.59
Headache	4	8.0	51	6.0	0.54
Nausea	4	8.0	51	6.0	1.00
Stomach Pain or Cramp	6	12.0	116	13.6	0.84
Red Skin	4	8.0	86	10.1	0.24
Vomiting	3	6.0	53	6.2	1.00
Symptoms Reported 60 Days Prior to Interview					
Diarrhea	16	32.0	167	19.5	0.04
Headache	6	12.0	131	15.3	0.69
Nausea	10	20.0	129	15.1	0.32
Stomach Pain or Cramp	17	34.0	230	26.9	0.33
Red Skin	7	14.0	150	17.5	0.26
Vomiting	12	24.0	159	18.6	0.35

* Analyses conducted on initial blood lead levels

**Fisher Exact Chi-Square test for significance

Table 11. Univariate Regression Models with Urine Arsenic Concentration as Dependent Variable

Independent variable	r^2	r	Regression coefficient	p*
Hours played inside	0.0009	0.0300	0.05110	0.39
Number of times objects inserted into mouth	0.0020	0.0447	-0.01125	0.21
Number of times fingers placed in mouth	0.0015	0.0387	-0.01068	0.28
Number of times hands washed	0.0014	0.0374	-0.07889	0.30
Number of times face washed	0.0032	0.0566	-0.18638	0.11
Percent of time hands washed before eating	0.0001	0.0100	-0.00298	0.74
Percent of time face washed before eating	0.0000	0.0000	0.00046	0.94
Percent of time hands washed before playing	0.0028	0.0529	-0.00610	0.14
Percent of time face washed before playing	0.0048	0.0693	-0.01130	0.05
Percent of time hands washed before bed	0.0163	0.1277	-0.02219	<0.001
Percent of time face washed before bed	0.0108	0.1039	-0.01709	<0.01
Percent of yard that is exposed dirt outside	0.0009	0.0300	0.00558	0.39
Residence length in months	0.0212	0.1456	0.04518	<0.001
Soil arsenic exposure (ppm-hr/week)	0.0004	0.0200	0.00632	0.58
Year residence built	0.0023	0.0480	0.00147	0.26
Mean residential soil arsenic concentration (ppm)	0.0009	0.0300	-0.00360	0.52

* Wilcoxon Rank-Sum test for significance

Table 12. Univariate Regression Models with Blood Lead Concentration as Dependent Variable

Independent variable	r^2	r	Regression coefficient	p*
Hours played inside	0.0000	0.0000	-0.00163	0.97
Number of times objects inserted into mouth	0.0017	0.0424	-0.00495	0.21
Number of times fingers placed in mouth	0.0004	0.0200	-0.00335	0.55
Number of times hands washed	0.0013	0.0361	0.04711	0.27
Number of times face washed	0.0014	0.0374	0.07336	0.26
Percent of time hands washed before eating	0.0000	0.0000	-0.00027	0.96
Percent of time face washed before eating	0.0011	0.0332	0.00346	0.31
Percent of time hands washed before playing	0.0012	0.0346	0.00445	0.30
Percent of time face washed before playing	0.0029	0.0539	0.00546	0.11
Percent of time hands washed before bed	0.0015	0.0387	-0.00418	0.24
Percent of time face washed before bed	0.0017	0.0412	-0.00427	0.21
Percent of yard that is exposed dirt outside	0.0012	0.0346	0.00386	0.30
Residence length in months	0.0064	0.0800	-0.01611	0.02
Soil lead exposure (ppm-hr/week)	0.0019	0.0436	0.00832	0.21
Year residence built	0.0008	0.0283	-0.00037	0.47
Mean residential soil lead concentration (ppm)	0.0234	0.1530	0.00356	<0.001

* Wilcoxon Rank-Sum test for significance

Table 13. Univariate Regression Models with Hair Arsenic Concentration as Dependent Variable

Independent variable	r^2	r	Regression coefficient	p*
Hours played inside	0.0079	0.0889	0.00218	0.57
Number of times objects inserted into mouth	0.0123	0.1109	0.00194	0.48
Number of times fingers placed in mouth	0.0689	0.2625	0.00420	0.09
Number of times hands washed	0.0012	0.0346	0.00093	0.83
Number of times face washed	0.0203	0.1425	0.00597	0.36
Percent of time hands washed before eating	0.0176	0.1327	0.00048	0.40
Percent of time face washed before eating	0.0143	0.1196	0.00023	0.45
Percent of time hands washed before playing	0.0126	0.1122	-0.00033	0.47
Percent of time face washed before playing	0.0022	0.0469	0.00009	0.77
Percent of time hands washed before bed	0.0006	0.0245	-0.00005	0.87
Percent of time face washed before bed	0.0010	0.0316	-0.00007	0.84
Percent of yard that is exposed dirt outside	0.0165	0.1285	-0.00036	0.41
Residence length in months	0.0875	0.2958	-0.00125	0.05
Soil arsenic exposure (ppm-hr/week)	0.0011	0.0332	-0.00010	0.84
Year residence built	0.0013	0.0361	-0.00012	0.83
Mean residential soil arsenic concentration (ppm)	0.0002	0.0141	-0.00005	0.93

* Wilcoxon Rank-Sum test for significance

APPENDIX B – STUDY INSTRUMENTS

"KIDS AT PLAY HEALTH SURVEY"

UNIVERSITY OF COLORADO HEALTH SCIENCES CENTER

Dear Resident,

In the next few days, interviewers from the University of Colorado Health Sciences Center will visit your home. As you may know, the Environmental Protection Agency has found higher than normal arsenic and lead levels in the soil in some yards in your neighborhood. Because young children are at highest risk from the toxic effects of arsenic and lead in soil, the University of Colorado Health Sciences Center has been asked by the Agency for Toxic Substances and Disease Registry and the Colorado Department of Public Health and Environment to do a health study of young children who may play in the soil.

As part of our study we will:

- Visit every home to identify all young children (ages 6 months to 6 years) who live in your neighborhood,
- Ask questions about their play behaviors,
- Offer to test the children for arsenic and lead. The tests are free. Parents or caregivers will be provided with results,
- Give you information to reduce exposures to arsenic and lead.

We will ask you questions about where you child usually plays, how long they play, and what they do while they play. If you remember these things, it will help us do a better job in our interview. The information from these interviews and tests will help us make sure children are not exposed to unsafe levels of arsenic and lead in soils. We will also hold community meetings over the summer to provide more information and to answer your questions about soil exposure and health effects of arsenic and lead.

We will be stopping by your home to see if you have young children and if you want to take part in the study. If you have any questions, please call (303) 296-0545.

Sincerely,

Kristina Kaparich
Project Director

3840 York St., Suite 218, Denver, CO 80205-3536
Ph. English: (303) 296-0545 * Ph. Spanish: (720) 314-4205 * Fax: (303) 298-0630

Kids at Play
Health Survey

SORRY WE MISSED YOU!

An interviewer from the University of Colorado Health Sciences Center stopped by your home today to see if you were willing to participate in a study of soil exposure to children that is being conducted in your neighborhood. We will stop by again in the next few days. If you have any questions about this survey, want to schedule an appointment with us or do not have any children, please call us at 303–296-0545 during the hours of 9 am to 8 pm.

¡LAMENTABLEMENTE NO LE ENCONTRAMOS!

Un entrevistador de la Universidad de Centro de las Ciencias para la Salud del Estado de Colorado

Kids at Play

Health Survey

SORRY WE MISSED YOU!

The staff from the University of Colorado Health Sciences Center stopped by this morning/afternoon/evening (circle one) for our scheduled interview/ sample collection. If you would like to reschedule your appointment, please call us at (303) 296-0545.

Thank you!

Census of Children

<table>
<tr><td colspan="6">Name of Parent Interviewed:</td></tr>
<tr><td colspan="3" rowspan="2">Street Number Street Name</td><td rowspan="2">Apt Number</td><td colspan="2">Type of Dwelling:</td></tr>
<tr><td>Single-family (S)
Multi-family (M)
Trailer (T)</td><td></td></tr>
<tr><td colspan="2">Home Phone Number:</td><td colspan="4">Work Phone Number:</td></tr>
<tr><td colspan="6">Census information for children 6 months to 6 years old:</td></tr>
<tr><td>First Name</td><td>Last Name</td><td>Sex (M/F)</td><td>Age</td><td colspan="2">Birth date (mm/dd/yyyy)</td></tr>
<tr><td></td><td></td><td></td><td></td><td colspan="2"></td></tr>
<tr><td></td><td></td><td></td><td></td><td colspan="2"></td></tr>
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<tr><td></td><td></td><td></td><td></td><td colspan="2"></td></tr>
</table>

Soil Exposure Questionnaire

<table>
<tr><td colspan="2">**Name of Adult Interviewed:**
________________ ________________
First **Last**
Name of Child: ________________ ________________
First **Last**</td><td>**Interviewer Initials:**</td><td>**Language of Interview (E,S,0):**</td></tr>
<tr><td colspan="2"></td><td colspan="2">**Date of Interview:**
_____/_____/_____/
MM DD YY</td></tr>
<tr><td colspan="2">**Child's Date of Birth:** _____/_____/_____/ *MM DD YYYY*
Child's Age: _____/_____/ *YY MM*
Child's Sex: **M F**</td><td colspan="2">**How long at this address?**
_____/_____/
YY MM</td></tr>
<tr><td colspan="4">**Child's Race/Ethnicity:**
Anglo____ Hispanic____ Black____ Asian____ American Indian____</td></tr>
<tr><td colspan="3">**Daily Activities for the Last 2 Weeks – Inside and Outside**</td><td>**Response**</td></tr>
<tr><td colspan="3">1. Hours per day child plays inside on floors</td><td></td></tr>
<tr><td colspan="3">2. Number of times per day child puts objects in mouth (toys, blankets, pacifier, etc.)</td><td></td></tr>
<tr><td colspan="3">3. Number of times per day child puts fingers in mouth or bites nails</td><td></td></tr>
<tr><td colspan="3">4. Usual number of times hands are washed in a day</td><td></td></tr>
<tr><td colspan="3">5. Usual number of times face is washed in a day</td><td></td></tr>
<tr><td colspan="3"></td><td>**Percent**</td></tr>
<tr><td colspan="3">6. Percent of time hands are washed before eating meals</td><td></td></tr>
</table>

7. Percent of time face is washed before eating meals	
8. Percent of time hands are washed after playing in dirt or sand	
9. Percent of time face is washed after playing in dirt or sand	
10. Percent of time hands are washed before going to bed	
11. Percent of time face is washed before going to bed	
12. Percent of time child plays outside on exposed sand or dirt (not on grass or pavement)	
	Yes/No
13. Does child eat vegetables grown in a neighborhood garden? (specify location in log)	
14. Have you ever seen your child eating dirt?	
14a. If yes, when was the last time?	
14b. How much dirt did your child eat (bottle cap, eraser, etc)?	
15. Is soil contact in past two weeks different from usual? (Same, More, Less)	

Outdoor Soil-Contact Activities and Locations

Location & Address (Locate number on map) >1/2 hr per day in the last 2 weeks	Activity Time per Week (hours)						Eating dirt		% exposed dirt (Interviewer)
	Total time	Playing with dirt	Eating or drinking	Thumb/ pacifier sucking/biting nails	Blanket/ Toy/other objects in mouth	Playing with pet	Times/day	Amount	
A.									
B.									
C.									
D.									
E.									

Addresses of Vegetable Garden Location(s)
V1.
V2.

Childhood Signs and Symptoms Survey

Name of Adult Interviewed:				Interviewer Initials:
Name of Child:				Date of Interview:
Has this child experienced:	*In the past 3 days*		*In the past 60 days*	
	Yes	No	Yes	No
Nausea (felt like vomiting, but did not)				
Vomiting				
Diarrhea				
Stomach pain or cramps				
Redness, swelling, or itching of skin				
Headache				
	Yes		No	
Has a doctor ever diagnosed your child with anemia:				

Dust and Paint Assessment

Play area

Where are your child's play or hiding places? ______________________

General

	No visible dirt/dust	Some visible dirt/dust	Lots of dirt/dust
Windowsills			
Floor			

Comments:

Paint Condition

	No Paint	Intact	Fair (some chipping/ peeling)	Poor – (lots of chipping/peeling)
Inside				
Windows				
Other Painted Wood				
Outside Paint				

Comments:

APPENDIX C – EDUCATIONAL MATERIALS

Arsenic in Soil

Soil and Your Health
Doctors and scientists from the Agency for Toxic Substances and Disease Registry (ATSDR) have looked at test results from soil collected in you neighborhood to see whether the amount of arsenic is high enough to cause health problems for people who live in the area. ATSDR found that the amount of arsenic in some yards might be a health concern for some children and adults.

How Can Arsenic Get into the Body?
Soil that contains arsenic can get into your body:

- While playing
- While gardening
- While working in your yard

We sometimes touch things that have dirt or dust on them and the put our hands or other items into our mouths. When this happens, small amounts of arsenic can get into our bodies along with the dirt or dust.

Swallowing these small amounts of soil with arsenic usually will not cause health problems. But if arsenic in soil is too high, children and adults might become sick.

Adults and Arsenic
Arsenic levels and cancer are a concern for people who grew up in a house with high levels of arsenic in soil and who continued to live in the house as adults. These people could have a higher chance of getting certain types of cancer, such as skin cancer and cancer of the lung, bladder, kidney, and liver.

Children and Arsenic
<u>Soil-Pica</u>
Some preschool children eat large amounts of soil (1 teaspoon or more) while playing and exploring their world. This is called soil-pica behavior.

Soil-pica behavior is especially a concern for children who live in areas with high arsenic levels in soil. After eating large amounts of soil with high levels of arsenic, these children could have health problems, such as:

- Nausea or upset stomach
- Stomach cramps
- Vomiting
- Diarrhea
- Swelling of the face (especially around the eyes)
- Headaches

You Can Protect Yourself

Here are a few things that you can do to protect your family from arsenic in the soil. These tips are especially important if you live in an area with high arsenic levels in soil. These tips are good steps for everyone to follow:

- Watch your preschool children when they are playing outside. Keep them from eating dirt or mud and from putting toys in their mouths.
- Talk to older children about the possible danger of eating soil.
- Encourage preschool children to play in areas of the yard that are covered by grass.
- Talk to adults about not eating soil or mud from their yards.

Where Can I Get More Information About Exposure to Arsenic in Soil and Soil-Pica Behavior?

Chris Poulet, ATSDR Denver
303-312-7012

Margaret Schonbeck, Colorado Department of Public Health and Environment
303-692-2636

Lead in Soil

Soil and Your Health
Doctors and scientists from the Agency for Toxic Substances and Disease Registry (ATSDR) have looked at test results from soil collected in you neighborhood to see whether the amount of lead is high enough to cause health problems for people who live in the area. ATSDR found that the amount of lead in some yards is at levels that are of concern for some children.

Common Sources of Lead

- *Soil*
- *Old house paint (especially houses built before 1960)*
- Dust
- *Plastic window blinds*
- Imported pottery/dishes
- Home remedies (Azarcon, Greta)
- Drinking water

How Can Lead Get into the Body?
Soil that contains lead can get into the body in many ways. When children play, they sometimes touch things that have dirt or dust on them and then put their hands or other items into their mouths. When this happens, small amounts of lead can get into their bodies along with the dirt or dust.

Swallowing small amounts of soil with lead usually will not cause health problems. But if the amount of lead in soil is too high, children might become sick.

Possible Health Effects from Lead
Most children with lead poisoning don't have symptoms. The only way to know if a child has lead poisoning is to get their blood tested. However, when children have high levels of lead in their bodies, they might have health problems, such as:

- Hearing problems
- Speech, language, and behavior problems
- Lowered intelligence scores
- Delays in development
- Trouble sleeping
- Poor muscle coordination
- Loss of appetite

Ways to Prevent Children from Getting Lead Poisoning

- Wash child's hands at least 5 times per day and always before eating and taking naps
- Wash toys frequently
- Give them foods rich in Vitamin C, calcium, and iron
- Clean floors and window sills with detergent and water
- Wipe up any paint chips with a wet sponge, rag, or paper towels. If you suspect the paint has lead, throw the sponge, rage, or paper towels away after cleaning
- If you are remodeling an older home, NEVER dry sand or scrape lead based paint
- Encourage your children to play in grassy areas instead of on dirt.

Where Can I Get More Information About Exposures to Lead in Soil?
If you think your child has been exposed to lead, you may contact:

Mishelle Macias
Colorado Department of Public Health and Environment
303-692-2622 or 303-692-2700

Gene Hook
City and County of Denver
720-865-5452

PROTECTING YOUR CHILD FROM LEAD-BASED PAINT

Is lead paint harmful to children?

A. Lead in paint is toxic and harmful to children. It can cause permanent problems to a child's brain, causing learning disabilities and behavioral problems.
B. Children under the age of six are most at risk.
C. When a pregnant woman is exposed to lead, it can harm her unborn baby.

Where is lead paint found?

A. Most homes built before 1978 have some lead paint. But, homes built before 1960 have the most lead paint.
B. Lead dust comes from damaged paint or scraping/sanding paint in older homes. Eventually, lead dust spreads throughout the home attaching to most surfaces.
C. Dirt or bare soil can also contain lead from paint that has peeled from the outside walls.

How are children poisoned from lead paint?

A. Children become exposed to paint chips and lead dust that settle on floors, windowsills, and other surfaces. It gets on their hands, on their toys, and in their mouths.
B. Playing in soil containing lead paint that has peeled from the outside walls can also poison children.
C. Most children exposed to lead don't have symptoms. The only way to know if a child has lead exposure is to get their blood tested.

What should I do if my child has been poisoned from lead paint?

A. First, locate any hazards in your home and learn how to eliminate them safely. **Never try to remove lead paint yourself.**
B. Get your child tested.
C. Talk to your health department about what else you can do to protect your children's health or call 1-888-LEADLIST for a list of lead service providers

How can you protect your children from lead paint exposure?

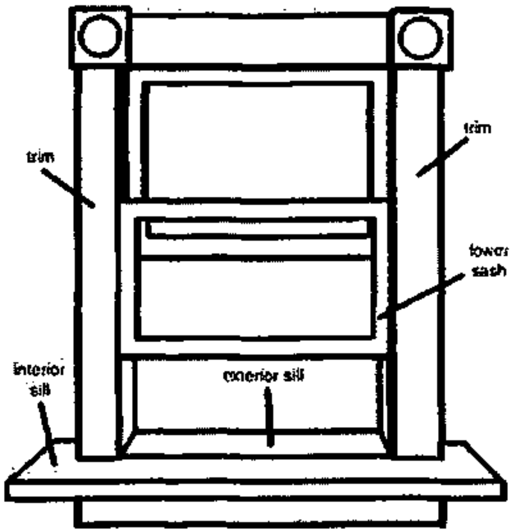
A. Keep your home free from lead dust! Clean floors and windowsills often with soap and water, and then rinse with fresh water.
B. Make sure children wash their hands before eating, after playing outside and at bedtime. Use soap and water.
C. Watch where your children play. Areas with grass or pavement are best. Exposed dirt near buildings may be contaminated with small paint chips.
D. Keep paint in good shape. Check for peeling and water damage and re-paint surfaces that have flaking paint.
E. Try never to remove lead paint yourself. But, if there is a situation where you have no choice, please work safely around it. Seal off the work area by covering furniture, floors, doors, windows and vents with heavy plastic, and keep women and children away from the work area. Remove flaking paint by sanding or scraping before re-painting. Wet down paint before you sand or scrape. Avoid creating lead dust and paint chips. Dispose of paint chips and dust in plastic bags place in trash bins immediately. Completely clean the work area with soap and water when done.

Should I worry about lead if I repaint or remodel?

A. Yes. Scraping, sanding or disturbing old paint can release large amounts of toxic lead dust. Learn to work safely with lead paint and make sure any contractor you hire follows lead-safe guidelines. For more information on "Reducing lead exposure when remodeling your home booklet," please call 1-800-424-LEAD, or call your local health department.

How can I protect my family from lead paint if I rent my home?
A. It is your landlord's responsibility to keep paint in good shape. If your landlord will not fix peeling or damaged paint, call your county health department. (health dept. number here) Landlords are required by law to give you information about lead paint before you sign the lease and at any time your rent is raised.
B. If your landlord fixes the flaking paint, make sure it is done properly, as described above. Make sure the workers who fix the paint do not spread lead paint chips or dust. Workers should clean up well before leaving.

KEEP YOUR CHILDREN SAFE FROM LEAD



Keep Your Kids Safe From Lead!

Windows are a major source of lead paint chips and dust. If your children are exposed to contaminated windows, they could be lead poisoned. By following some simple steps, you can reduce the risk of lead hazards and keep your kids

Here's How:

1. **Raise and secure the lower sash** (as seen in the diagram) of each window. This will expose the exterior sill, the flat portion of the window frame shown in the picture.

2. **Remove and wash any toys** found in the windowsills with soapy water.

3. **Remove paint chips and dirt from windows with wet paper towels** or rags and dispose of them immediately in a secure trash bag.

4. Use a bucket full of soapy water and rags or paper towels to **clean out all remaining dirt, paint, and debris from all exterior sills.** Repeat until all areas are completely clean. Dispose of rags or paper towels in a secure trash bag.

5. Use clean rags and water to **wipe down the trim and interior sill of each window.** These are the decorative portions of the window facing the inside of the house (as seen in the picture). Wash the trim and sill from top to bottom and dispose of rags in a secure trash bag.

6. When you are done cleaning all the windows in your home, **flush the soap water down the toilet.**

7. **Repeat these steps every two weeks.** It may be necessary to clean the windows more often in warm weather, or at windows that your children are in greater contact with.

APPDENIX D – CONSENT FORM

Consent Form Approval

Date: Valid Through:__________

COLORADO MULTIPLE INSTITUTIONAL REVIEW BOARD

Survey of Soil Arsenic and Lead Exposure among Residents in VBI-70 Neighborhoods 01-786

Principal Investigator: A. James Ruttenber, MD, PhD

SUBJECT CONSENT FORM
Last Revised May 15, 2002

1. Project Description

You are being asked to take part in a research study that will assess exposures to soil for children in your neighborhood. This study is sponsored by the Agency for Toxic Substance and Disease Registries and Colorado Department of Public Health and Environment, and conducted by the University of Colorado Health Sciences Center. The study is being conducted because soil arsenic and lead concentrations are higher than normal in your neighborhood, and the sponsoring agencies want to gather more information to help them determine the best ways to protect residents from exposure to these chemicals.

For this study, we will identify the children between 6 months and 6 years old who live in your neighborhood. We will then ask a few questions about these children--where they play outdoors, and how often they come in contact with soil. We will then offer to collect a sample of urine to test for arsenic and a small sample of blood to test for lead. We will report the results to parents within 2 weeks of collecting the sample, and use the information to help make sure that children are not exposed to unsafe levels of arsenic and lead. We are planning to enroll 2,800 children from your neighborhood in this study.

Although we are requesting that you and your child or children participate in all parts of this study, you may elect to participate or not participate in any of the parts.

Participation in this survey is voluntary and your child or children will suffer no consequences nor will their medical care be different if you do not agree to participate.

2. Procedures

If you agree to take part in this study, we will ask you to:

2.1 Provide us with your name, address and phone number(s), and the names and ages of your children who are between the ages of 6 months and 6 years old;

2.2 Answer a few questions about each child's daily activities. It will take about 15 minutes for you to answer these questions for each child;

2.3 Collect a sample of urine from each child to test for arsenic levels. For the test of arsenic to be accurate, the child who is tested must not have eaten seafood or other fish for at least 3 days before providing a urine sample. Also, the urine sample must be collected first thing in the morning.

The results of the urine test will be reported to you within 2 weeks of sample collection. Results will also be provided to your child's physician. If the arsenic concentrations are higher than normal, we will request to collect an additional sample to confirm the first finding. The repeat urine sample will be collected in the same way as the first. You do not have to have the test repeated if you don't want to.

2.4 Allow us to collect a sample of a few drops of blood by pricking your child's finger with a small needle. A staff person will collect the blood sample at the time the urine sample is picked up, or at a time that is more convenient for you. The staff person who collects the blood sample has been trained to do this by experts at the Colorado Department of Public Health and Environment.

The results for this analysis will be reported to you within 2 weeks of sample collection. Results will also be provided to your child's physician. If the concentration of lead in the blood sample is higher than normal, we will request that a repeat blood sample be collected from your child's arm by venipuncture–a routine procedure that withdraws about a teaspoon of blood from a vein in your child's arm. The blood sample will be collected by a health professional trained in this procedure, at a medical clinic near your neighborhood. A staff person from the study will schedule an appointment for your child. You do not have to have the test repeated if you don't want to.

2.5 We might also ask that your child provide an additional sample of urine and a small amount of hair to help us check on our lab procedures for the arsenic test. The urine sample will be collected in the manner described above. The hair sample will be cut close to the scalp from an area that will not be noticed. We will remove about 100 strands of hair–about the thickness of a soda straw. You do not have to participate in this part of the study if you don't want to.

3. Discomforts and Risks

Only minimal discomforts or risks to children are expected in this study. Children who have the blood lead test will have a finger pricked with a needle, just enough to get a few drops of blood. The finger prick can be uncomfortable, and cause mild pain in children, but the pain normally goes away within a few minutes.

Initial ________

If blood is collected by venipuncture, a bruise may form at the site of collection. The bruise will go away in a few days.

4. Benefits
This study is designed for public health agencies to learn more about soil exposure so they can make sure children are not exposed to unsafe amounts of arsenic and lead. This study is not designed to treat any illness or to improve your health. Also, there are risks as mentioned in the Risk Section.

5. Source of Funding
Funding for this study is provided by the Agency for Toxic Substances and Disease Registry (ATSDR), a federal public health organization located in Atlanta, Georgia.

6. Cost to Subject
There is no cost to you for participating in this study. There will be no charge for the urinary arsenic and blood lead tests. You will not be paid for your participation in the study.

7. Withdrawal from Study
Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you do not take part in the study, your doctor will still take care of you and your children. You and your children will not lose any benefits or medical care to which you are entitled. If you choose to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you and your children want to continue to take part, you will be told about them. The study doctor may decide to stop your child's participation without your permission, if he or she thinks that being in the study may cause him or her harm, or for any other reason. Also the sponsor may stop the study at any time.

The researcher carrying out this study is Dr. James Ruttenber. You may ask any questions you have now or in the future. If you have questions later, you may call Dr. Ruttenber at (303) 315-5627. You will be given a copy of this consent form to keep. If you have questions regarding your rights as a research subject, please call the Colorado Multiple Institutional Review Board (COMIRB) office at (303) 724-1055.

8. Confidentiality Protection
We will make every effort to keep your research records confidential, but it cannot be assured. Records that identify you (including your medical records) and the consent form signed by you, may be looked at by a regulatory agency such as the U.S. Department of Health and Human Services and the Colorado Multiple Institution Review Board. Your records may also be looked at by ATSDR. These agencies will not identify you or your children in any reports that may be released to the public

The results of this research may be presented at meetings or in published articles. However, your name and the names of your children will be kept private.

Initial ________

9. Authorization
I have read this paper about the study or it was read to me. I understand the possible risk and benefits of this study. I know that being in this study is voluntary. I choose to be (or choose to have my child) in this study. I know I can stop being a part of this study and I (or my child) will still get the usual medical care. I will get and be able to keep a copy of this consent form. (Initial all the previous pages of the consent form).

I agree to participate in the parts of the study that I have initialed below:

__________ the census of children, as described in Section 2.1 above

I agree to have my child, named ____ participate in:

_________ the daily activity survey, as described in Section 2.2 above,

_________ the test for arsenic concentration in urine, as described in Section 2.3 above,

_________ the test for lead concentration in blood, as described in Section 2.4 above,

______ the additional sample of urine and the collection of hair, as described in Section 2.5 above.

Signature:______________________________________ Date: ________

parent or guardian

Print name:______________________________________

Consent form explained by:______________________________ Date:________

signature

Print name: ______________________________

Investigator:______________________________________ Date:_______

signature

Print name:______________________________________

APPDENIX E – QA/QC PROCEDURES

SAMPLE ANALYSIS AND QUALITY ASSURANCE PLAN

for

URINARY ARSENIC AND BLOOD LEAD
AMONG RESIDENTS OF VBI-70 NEIGHBORHOODS

June 2002

Produced by:

US Environmental Protection Agency, Region 8
999 18th Street, Suite 300
Denver CO 80202

With technical assistance from:

Syracuse Research Corporation
999 18th Street, Suite 1975
Denver CO 80202

APPROVAL PAGE

This Sampling Analysis and Quality Assurance Project Plan, written for the University of Colorado Health Science Center arsenic/lead exposure and biomonitoring study, has been prepared at the request of the U.S. Environmental Protection Agency, Region 8, by Syracuse Research Corporation. Study investigations and activities addressed in this Project Plan are approved without condition.

Technical Approval Bonnie Lavelle USEPA Project Manager	Date
William Brattin, PhD Syracuse Research Corporation	Date

1.0 INTRODUCTION

USEPA Region 8 will assist the University of Colorado Health Science Center (UCHSC) in their survey of soil arsenic and lead exposure among residents of VBI-70 neighborhoods and will be responsible for the chemical analysis of all samples collected during the survey. This document details the sample handing, analysis, and quality assurance procedures that will be followed during this support activity.

2.0 ANALYSIS OF URINE

Samples of urine will be collected by UCHSC staff from study participants in accord with the protocols described in Appendices G, H, and I. Each collection container will be labeled in the field with a unique sample identification number using the following format:

UCHSC VBI-70 Uxxxx

One copy of the label will be applied directly to the sample collection vessel. A second copy of the label will be applied to the survey form used to record the name and address of the sample donor. A third copy of the label will be used to label the sample tube shipped to the laboratory (see below).

2.1 Sample Holding and Preparation

a. Each urine sample will be held under refrigeration at approximately 4°C in its original collection container. Under these conditions, the holding time for un-preserved urine is 3 months. Samples should be maintained in a restricted access area at all times

b. Either daily or once per week (whichever is most convenient), all samples scheduled for analysis will be well mixed by swirling the urine container, and 3-4 mL will be removed by pipette and transferred to a 15-mL plastic screw-cap tube. This tube will be labeled with the same number as that given to the original parent sample (see above). After transfer of the aliquot, the cap of the tube will be screwed on tight to prevent leakage, and the tube will be placed in a test tube rack. This sub-sample will be submitted to the analytical laboratory for analysis. The remainder of the sample will be stored in a refrigerator until the sample has been successfully analyzed by the laboratory.

2.2 Sample Shipment to the Laboratory

Packaging

Samples will be packaged for shipment to the analytical laboratory in test tube racks. Each rack of tubes will be placed inside a large plastic bag to ensure that the tubes do not fall out of the rack and to help contain any spills or leaks. Sealed bags will be placed in a cooler and secured against excess movement by addition of plastic bubble wrap. Adsorbent material should be added around the bags in case of any spills or leaks. The cooler will be kept cool by inclusion of 3-4 frozen "blue ice" packages. Once filled, the cooler will be sealed with tape and a signed custody seal will be placed across the opening of the shipping container in order to ensure that no tampering occurs during the shipping process.

Shipping

National Medical Services (NMS) will perform all analyses for urinary arsenic. The shipping address and contact information is presented below:

National Medical Services
3701 Welsh Rd
P.O. Box 433A
Willow Grove, Pennsylvania 19090-0437
1-800-522-6671

Each cooler will be shipped to the laboratory by overnight transport. The laboratory shall be notified by phone to expect each shipment, and shipping should always occur so that someone is present at the laboratory to receive the shipment. Shipment on a Monday or Tuesday is generally preferred.

No special labeling is required for urine samples.

Chain of Custody
Each cooler shipped to the laboratory will be accompanied by a Chain of Custody (COC) form. These COC forms are to be prepared in triplicate on carbonless forms using the approach specified in SOP No. MK-VBI-70-02. SRC will provide the field team with COC forms. Each COC form will identify the samples included in the sample delivery group (SDG) (i.e., in the cooler) and the required analyses. Each complete COC form will be reviewed for accuracy and clarity by UCHSC staff before shipment, and then signed. The pink (bottom) copy of the

form will be kept by UCHSC as documentation of the date and contents of the shipment. The white (top) and yellow (middle) copies of the COC form will be sealed inside the shipping container but inside a plastic zip-lock bag to avoid damage from moisture.

When the cooler arrives at the laboratory, the laboratory sample custodian will document the date and time of receipt. The cooler will be opened and the contents inspected. The chain-of custody form will be reviewed, and any tubes that are missing, broken, or otherwise questionable or compromised will be noted on the COC form. The laboratory will notify EPA's contractor (Syracuse Research Corporation, SRC) of any such problems immediately, and SRC will instruct the laboratory or arrange for replacement samples to be shipped, as needed. Once all samples have been reviewed and all issues have been resolved, the laboratory sample custodian will sign and date the COC form. Both remaining COC form copies (white and yellow) will be appropriately filed by the laboratory sample custodian.

2.3 Sample Analysis

2.3.1 Total Non-Dietary (Inorganic) Arsenic

All samples of urine will be analyzed for total non-dietary arsenic. This total includes both trivalent and pentavalent forms of inorganic arsenic (As+3, As+5), as well as the primary urinary metabolites of these forms (monomethyarsonate (MMA), and dimethylarsinate (DMA)). Complex organic arsenicals found in seafood (e.g., arsenobetaine) are not included in the total.

Details of the sample preparation and analysis are proprietary. In general, iodine is added to the sample and the target analytes are extracted into an organic phase under acidic conditions. A portion of this extract is analyzed for arsenic via ICP-MS. The detection limit is approximately 1.0 ug/L.

Each urine sample will also be analyzed for creatinine.

2.3.2 Total Urinary Arsenic

In some cases, samples of urine may require re-analysis to determine if an elevated level of arsenic might be due to dietary arsenic. SRC will identify samples requiring total urinary arsenic analysis and provide the list of samples to the laboratory.

NMS will analyze specified urine samples for total arsenic by ICP-MS. This method detects all forms of arsenic, including arsenobetaine and other related organic forms that occur in the diet. Details of the analytical method used by NMS for total urinary arsenic analysis are proprietary.

The detection limit is approximately 1 ug/L. Data will be reported to SRC as above.

2.4 Quality Control

Quality Control (QC) consists of the collection of data that allow a quantitative evaluation of the accuracy and precision of the data collected during the project. QC samples that will be collected for urinary arsenic during this project include the following types of samples:

Laboratory-Based QC Samples

The analytical laboratory will collect several types of data that help assess the accuracy and precision of the sample preparation and analysis procedure. The analytical laboratory will use BioRad laboratory control samples. These samples are prepared from human urine and contain inorganic and organic forms of arsenic. Specifically, following each calibration of the instrument, the analytical laboratory will analyze one blank, one BioRad Level 1 (target = 56 ug/L, range 42 - 70ug/L), and one BioRad Level 2 (target = 137 ug/L, range 103-172 ug/L) laboratory control sample. After every 10 analyses, the analytical laboratory will analyze one LCS, alternating between high and low levels. Furthermore, one non-dietary LCS (certified for MMA, DMA, As+5) and one dietary LCS (certified for MMA, DMA, As+5, and arsenobetaine) will be analyzed once a week to ensure the inorganic arsenic is correctly extracted and no dietary arsenic is included in the analyses. If any of the LCS values are outside the specified acceptance criteria (2 standard deviations from the mean based on 20 measurements), all samples analyzed since the last successful LCS analysis will be re-analyzed.

Field-Based QC Samples

Field-based QC samples are samples that are prepared by the study team and are submitted to the analytical laboratory in a blind fashion. That is, the laboratory is not aware the sample is a QC sample, and should treat the sample in the same way as a field sample. Two types of blind field QC sample will be submitted in this program:

Field Splits

A field spilt sample is prepared by withdrawing a second 3-4 mL aliquot of a parent urine sample and submitting that to the laboratory under a different (and unique) sample number from the first aliquot. The results of field split sample analysis help evaluate analytical precision (reproducibility). Split samples will be prepared at a rate of approximately 5%, and submitted in random order.

PE Samples

Performance Evaluation (PE) samples are samples of urine that contain a known and certified level of a contaminant. The results of PE sample analysis help evaluate analytical accuracy. In brief, the "blank" PE sample were prepared by collecting urine from adult volunteers who had not ingested seafood for at least three days. Note that the concentration of total inorganic arsenic in this sample is not zero, but is about 4 ug/L. Other PE samples were be prepared by spiking this "blank" urine with known incremental concentrations (5 ug arsenic/L and 15 ug arsenic/L) of sodium arsenate (As+5), sodium arsenite (As+3), monomethylarsonate (MMA), dimethylarsenate (DMA), or arsenobetaine. One concentration (20 ug/L) of arsenobetaine was prepared. Thus, there are a total of 10 different PE samples for this program. Nominal concentrations for each PE sample were established by the laboratory preparing the PE samples. These results are shown in Table 1.

As part of the first sample shipment, two samples of each of these 10 PE samples will be submitted in random order. For subsequent weekly shipments, one of each standard type will be submitted in random order.

QC Acceptance Criteria

The acceptance criterion for field split samples is a Relative Percent Difference (RPD) of no more than 30%. This acceptance criterion may be revised as data become available.

For all PE samples except arsenobetaine analyzed for total inorganic arsenic, the acceptance criteria will be ± 20% of the nominal value shown in Table 1. For arsenobetaine analyzed for total inorganic arsenic, the acceptance criteria are equal to the criteria for blank urine, with an increment of no more than 10% of the spiked arsenobetaine level. For the arsenobetaine PE sample analyzed for total arsenic, the acceptance criteria is ± 20% of the nominal value shown in Table 1. These acceptance criteria may be revised as data become available.

QC Assessment and Response Actions

Results for QC samples will be reviewed by SRC promptly upon receipt from the laboratory. Any deviation of a QC sample from the acceptance criteria above will be evaluated and a corrective action selected. If deviations are minor (only slightly outside the acceptance bounds) and are not consistent over time or sample type, no action will be required. If deviations are consistent (occurring in two or more consecutive weeks) or if deviations are not trivial, SRC will immediately contact the laboratory to discuss possible causes and appropriate laboratory corrective actions.

2.5 Reporting

NMS will submit a weekly report to SRC which includes a Microsoft Excel summary of the results for each sample, including the total inorganic arsenic concentration (ug/L), urinary creatinine concentration (g/L), and total inorganic arsenic concentration normalized for creatinine (ug/g). The report will also include a summary of the laboratory QC samples for each SDG.

3.0 ANALYSIS OF BLOOD

3.1 Sample Collection

In brief, the tip of the participant's finger is carefully washed and dried, and the finger is pierced using a sterile lancet. Once a drop of blood has collected on the finger tip, the blood is drawn into a plastic capillary tube that is held in a microtainer. When the capillary is filled, the capillary is tipped upright, allowing the blood to drain into the microtainer. The capillary and the lancet are discarded as biomedical waste, and the microtainer is sealed with the attached cap.

Each microtainer will be assigned a unique sample identifier using the following format :

UCHSC VBI-70 Bxxxx

One copy of the label is applied to the microtainer by wrapping it around the bottom portion of the microtainer. A second copy of the label is applied to the field survey form that records the name and address of the sample donor. A database will be used to record and correlate the sample identification number and the name and address of the sample donor.

All microtainers will be stored in bubble wrap envelopes (20-25 microtainers per envelope) and stored refrigerated at 4°C.

3.2 Sample Preparation

No sample preparation is necessary prior to sample shipment.

3.3 Sample Shipment to the Laboratory

Packaging

Samples will be shipped to the analytical laboratory in plastic bubble wrap envelopes. Each envelope will be sealed to ensure that the tubes do not fall out during shipment. Envelopes will be placed in a cooler and secured against excess movement by addition of extra plastic bubble wrap. The cooler will be kept cool by inclusion of 3-4 frozen "blue ice" packages. Once filled, the cooler will be sealed with tape and a signed custody seal will be placed across the opening of the shipping container in order to ensure that no tampering occurs during the shipping process.

Shipping

All analyses of blood will be performed by Tamarac Medical, Inc. The shipping address and contact information for the laboratory are provided below:

Tamarac Medical, Inc.
7000 South Broadway #2C
Littleton, CO 80122
(800) 842-7069

Delivery of the samples from UCHSC to the laboratory will occur about once per week. Transport will normally by courier sent from the laboratory. UCHSC staff will contact the laboratory when a shipment is ready, and arrange for the details of the shipment. In the event that this method is not available, a UCHSC staff member will contact the laboratory and transport the samples to the analytical facility at an agreed upon time.

Chain of Custody
Each cooler shipped to the laboratory will be accompanied by a Chain of Custody (COC) form. These COC forms are to be prepared in triplicate on carbonless forms using the approach specified in SOP No. MK-VBI-70-02. Each COC form will identify the samples included in the sample delivery group (SDG) (i.e., in the cooler) and the required analyses. Each complete COC form will be reviewed for accuracy and clarity by UCHSC staff before shipment, and then signed.

One copy of the form will be kept by UCHSC as documentation of the date and contents of the shipment. The other copies of the COC form will be sealed inside the shipping container but inside a plastic zip-lock bag to avoid damage from moisture.

When the cooler arrives at the laboratory, the laboratory sample custodian will document the date and time of receipt. The cooler will be opened and the contents inspected. The chain-of custody form will be reviewed, and any tubes that are missing, open, or otherwise questionable or compromised will be noted. The laboratory will notify SRC of any such problems immediately.

3.4 Sample Analysis

Each blood sample will be analyzed for lead using the method of Miller (1987). See SOP # 01 for method details. In brief, the method uses graphite furnace atomic absorption spectrometry

(GFAAS) to analyze blood samples for lead. In order to stabilize the blood, all blood samples will be combined with known volumes of Metexchange reagent. This method requires a minimum volume of 50 uL of blood, with 100 uL being desirable. The detection limit is 2.0 ug/dL.

3.5 Quality Assurance

Laboratory-Based QC Samples

Following each calibration, Tamarac will analyze one low (8.0 ug/dL), one medium (20.0 ug/dL), and one high (40.0 ug/dL) LCS. Upon a successful run, Tamarac will analyze a one set of 10 field samples followed by two sets of 11 field samples. Following each series, Tamarac will analyze one medium and one high LCS. Once each series of samples have been analyzed with all LCS samples passing established acceptance criteria, Tamarac will re-calibrate the machine and repeat the steps above. The acceptance criterion is defined as an LCS that is within 2.0 ug/dL of the nominal concentration.

In the event that a QC sample result is outside the acceptance criteria, Tamarac will re-calibrate the machine and re-analyze the LCS. If the LCS fails twice, Tamarac will stop the machine and take appropriate measures to correct the problem.

Field-Based QC Samples

Field Duplicate

Field duplicate samples are collected at the same time as the primary sample. In this case, the field duplicate sample is a second sample of blood drawn from the same individual, by filling a second capillary tube immediately after filling the first tube. These samples will be collected opportunistically from those individuals with sufficient blood flow after a single finger prick. Each field duplicate sample is assigned a unique sample identifier that is not related to the sample identifier for the primary field sample. Field duplicate samples will be collected and submitted in random order at a frequency of about 5%, if possible.

PE Samples

PE samples for blood lead analysis will be provided by the Centers for Disease Control and Prevention. Consensus (nominal) concentrations of lead in these samples were determined by CDC using GFAAS or ICP-MS. A summary of these samples is listed below:

CDC Sample ID	Nominal Value (ug/dL)
194	0.4
1494	4.5
994	8.9
396	14.8

PE samples will be prepared for submittal to the laboratory by withdrawing 50-75 uL samples from the CDC stock samples using the sample capillary sampling device as is used to collect blood samples from program participants. Microtainers containing PE samples will be assigned random sample numbers and submitted blind to the laboratory along with the field samples. Each week, one sample of each PE sample above (i.e., a total of 4) will be submitted. In the first shipment of samples, two of each PE sample will be submitted.

QC Acceptance Criteria

Field Duplicates

The acceptance criterion for field split samples is a maximum difference of 2.0 ug/dL between the primary sample and the field duplicate sample. This acceptance criteria value may be revised as data become available.

PE Samples

In accord with recommendations from CDC, the acceptance criterion for all blood PE samples with nominal concentrations below 40 ug/dL is ± 4 ug/dL. This acceptance criteria value may be revised as data become available.

QC Assessment and Response Actions

Results for QC samples will be reviewed by SRC promptly upon receipt from the laboratory. Any deviation of a QC sample from the acceptance criteria above will be evaluated and a corrective action selected. If deviations are minor (only slightly outside the acceptance bounds) and are not consistent over time or sample type, no action will be required. If deviations are consistent (occurring in two or more consecutive weeks) or if deviations are not trivial, SRC will immediately contact the laboratory to discuss possible causes and appropriate laboratory corrective actions.

3.6 Reporting

Tamarac will provide EPA's contractor (SRC) a weekly electronic (Microsoft Excel) report of sample results and a hard copy machine printout of all QC results. Results will be delivered to SRC via email. However, any sample results above 10 ug/dL will either be phoned or faxed to SRC immediately following sample analysis.

When a sample of blood from a program participant is reported to exceed a value of 10 ug/dL, SRC will promptly report the sample number, name, and address to UCHSC staff, who will seek to arrange for collection of a second (confirmation) sample from the individual. Whenever possible, this sample will be a venous sample collected in a vacutainer by a trained pediatric phlebotomist. This sample will be submitted to Tamarac with a unique identifier number for analysis for lead, as above. If the second sample confirms a blood lead level above 10 ug/dL, SRC will provide Tamarac with the name and address of the donor, and in accord with Colorado State law (6 CCR-1009-7), Tamarac will report the value to the Colorado Department of Public Health and Environment (CDPHE) within 30 days.

5.0 FIELD AUDIT ACTIVITIES

As part of the overall Quality Assurance Plan for this project, EPA will provide random audits of field data and sample collection procedures by UCHSC staff. This will include ensuring that all surveys are administered properly and that responses are recorded correctly and with consistency between different teams, that biological samples are collected properly, and that biological sample identifier information is correct and complete. Audits will include observations of each different field team's activities, including initial visits and return visits for repeat sample collection. Audits will be concentrated in the beginning of the program, but will continue at random times throughout the program.

Any issues or problems observed by the field auditors will be reported to EPA and the UCHSC team leader, both verbally and in written (memo) form, along with any suggestions for addressing those problems.

6.0 REFERENCES

Colorado Department of Public Health and Environment (CDPHE). 1999. Rules and regulations pertaining to the detection, monitoring, and investigation of environmental and chronic diseases. http://www.cdphe.state.co.us/op/regs/100907.pdf

Miller et al. 1987. Determination of lead in blood using electrothermal atomic absorption spectrometry, l'vov platform, and matrix modifier. Analyst 112:1701-1704

TABLE 1
NOMINAL VALUES AND ACCEPTANCE CRITERIA FOR URINE PE SAMPLES

Spiking Material	Spiked Level (ug As/L)	Measured Conc (ug As/L)		Acceptance Criteria (ug/L)		
		mean	stdev	Method	Low	High
None	--	4.4	0.4	a, b	3.5	5.3
As(+3)	5	9.6	0.2	a, b	7.7	11.6
	15	20.7	0.6	a, b	16.5	24.8
As(+5)	5	10.3	0.6	a, b	8.3	12.4
	15	20.0	0.0	a, b	16.0	24.0
MMA	5	7.4	0.3	a, b	5.9	8.9
	15	14.7	0.6	a, b	11.7	17.6
DMA	5	8.6	0.3	a, b	6.9	10.3
	15	17.0	0.0	a, b	13.6	20.4
Arsenobetaine	20	24.3	0.6	a	3.5	7.3
				b	19.5	29.2

a = Total inorganic (non-dietary) arsenic
b = Total arsenic

Urine Collection Instructions For Children Not in Diapers

1. **Please make sure your child has not eaten any seafood or other fish for the last 3 days.** This includes:
   - Fish
   - Canned tunafish
   - Salmon
   - Shrimp
   - Oysters
   - Crab
   - Clams

2. If your child has eaten seafood in the 3 days before the urine test, you will need to wait 3 days before you collect your child's urine sample.

3. We realize that it is very hard to collect a urine sample from a small child. Please try to do so, because without the urine sample we will not be able to test the child for arsenic exposure. **Please call 303-296-0545 if you have any questions**.

4. Be sure that *the name on the cup matches* the *name of the child* whose urine is being collected.

5. **Wash your hands with soap** and water immediately before collecting the sample.

6. **Do not** open the collection cup until just before the child urinates.

7. It is very important that the inside of the cup and the lid not be touched with any part of the body or with clothing.

8. Remove the *lid* and *leave it turned up* on a flat surface.

9. **Clean the child's genitals** with the towelet provided.

10. Collect the child's **first morning urine** in the cup by having the child urinate into the cup. Try to fill the cup at least 2/3 full.

11. *Immediately put the lid back on* the filled urine cup.

12. Make sure the urine cup is closed tightly. *Place the filled cup inside the ziplock bag* and seal the bag.

13. Immediately put the cup in the refrigerator. Leave it there until a "Kids at Play Health Survey" team member returns to pick up the cup.

Urine Collection Instructions For Children in Diapers

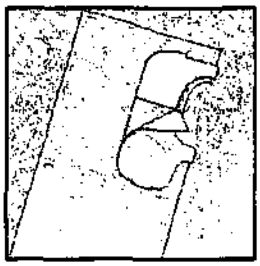
1. **Please make sure your child has not eaten any seafood or other fish for the last 3 days.** This includes:
   - Fish
   - Canned tunafish
   - Salmon
   - Shrimp
   - Oysters
   - Crab
   - Clams
2. Please apply the bag at the time that the last diaper is applied before putting the child to sleep for the night.

3. We realize that it is very difficult to collect a urine sample from a small child. Please try to do so, because without the urine sample we will not be able to test the child for arsenic exposure. **Please call 303-296-0545 if you have any questions.**

4. **Wash hands thoroughly** before you begin to apply the urine collector. Make sure the area you are working in is clean such as (a clean towel or clean paper towels).

5. Separate the child's legs **and thoroughly wash the whole area between the legs with soap and water. Do not** use any baby powders, oils, or lotions.

6. Take the urine collector and peel off the lower half of the adhesive paper.



7. Stretch the skin to remove skin folds.

   For Females: Place the adhesive between the vagina and the anus. Smooth out the lower half of the adhesive. Try to avoid making wrinkles in the adhesive because they may cause urine to leak out. Remove the upper part of the adhesive paper and smooth it against the skin.

   For Males: Place the adhesive between the scrotum and the anus. Put the penis through the bag. Smooth out the lower half of the adhesive. Try to avoid making wrinkles in the adhesive because they may cause urine to leak out. Remove the upper part of the adhesive paper and smooth it against the skin.

6. Apply the diaper directly over the bag.

7. As soon as the child wakes up in the morning:

   - Get the urine cup and be sure that the name on the cup matches the name of the child whose urine is being collected.

   - **Wash your hands with soap and water immediately before collecting the sample.**

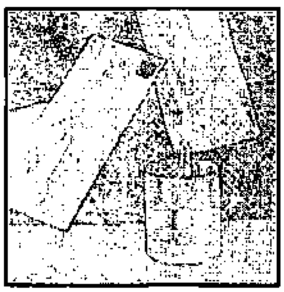
   - **Do not** open the collection cup until it is needed.

   - It is *very important that the inside of the cup and the lid not be touched* with any part of the body or with clothing.

   - *Remove the lid and leave it turned up* on a flat surface.

   - *Open the diaper and carefully remove the bag.* This is best done by one person holding the child upright in a slight forward leaning position, while another person removes the bag. Begin by gently unpeeling from the top of the bag (the part closest to the belly button) and proceed to unpeel the bag down towards the legs. Be sure not to tip the bag and spill the urine.

   - Pull off the blue tab and pour the urine into the urine cup.



   - *Immediately recap* the filled container.

   - Be sure the urine cup is *capped tightly.* Place the filled *container inside the ziplock bag* and seal the bag.

   - Immediately put *the cup in the refrigerator.* Leave it there until a "Kids at Play Health Survey" team member returns to pick up the cup.

APPENDIX F – REPORTING RESULTS LETTER

"KIDS AT PLAY HEALTH SURVEY"

UNIVERSITY OF COLORADO HEALTH SCIENCES CENTER

Date:

Dear «Name»,

The University of Colorado Health Sciences Center wishes to thank you for participating in the survey of arsenic exposure conducted this summer.

Your urine arsenic level was: «Result» µg/L –a concentration that is considered normal. Health experts have determined that a safe level for urine arsenic is 29 micrograms per Liter (µg/L) or less.

If you have any questions concerning your test results, or if you want more information about the study or exposure to arsenic in soil, please call our project director, Kristina Kaparich, at 303-296-0545.

In order to follow-up on any concerns or questions you might have about our study, we are providing a series of community meetings to answer your questions, and to distribute literature on arsenic and lead exposure.

There will be a Spanish translator present for anyone whose primary language is Spanish. We will also have refreshments. The community meetings are open to anyone interested in learning more about our study. If you have any questions, please call (303) 296-0545.

Next Community Meeting and Locations:

- **Date:** July 29, 2002 **Time**: 7-8:30PM — **Place**: Inner City Development Community Corporation
  3840 York Street, Suite 130
  Denver, CO
  (303)296-0545
  Contact: Christine Alvarez

Sincerely,

JIM RUTTENBER, Ph.D., M.D.
Principal Investigator

3840 York St., Suite 218, Denver, CO 80205-3536
Ph. Eng: (303) 296-0545 * Ph. Span: (720) 314-4205 * Fax: (303) 298-0630

"KIDS AT PLAY HEALTH SURVEY"

UNIVERSITY OF COLORADO HEALTH SCIENCES CENTER

Date:

Dear «Name»,

The University of Colorado Health Sciences Center wishes to thank you for participating in the survey of lead exposure conducted this summer.

Your results showed a blood lead level of: <u>«Result»</u> micrograms per deciliter (μg/dL) - a blood lead level that is considered safe. A blood lead level of 10μg/dL or greater is considered elevated. Therefore, your blood lead level is below the level of concern.

If you have any questions concerning your test results, or if you want more information about the study or exposure to lead in soil please call our project director, Kristina Kaparich, at 303-296-0545.

In order to follow-up on any concerns or questions you might have about our study, we are providing a series of community meetings to answer your questions, and to distribute literature on arsenic and lead exposure.

There will be a Spanish translator present for anyone whose primary language is Spanish. We will also have refreshments. The community meetings are open to anyone interested in learning more about our study. If you have any questions, please call (303) 296-0545.

Next Community Meeting and Location:

- **Date:** July 29, 2002 **Time**: 7-8:30PM — **Place**: Inner City Development Community Corporation
3840 York Street, Suite 130
Denver, CO
(303)296-0545
Contact: Christine Alvarez

Sincerely,

JIM RUTTENBER, Ph.D., M.D.
Principal Investigator

3840 York St., Suite 218, Denver, CO 80205-3536
Ph. Eng: (303) 296-0545 * Ph. Span: (720) 314-4205 * Fax: (303) 298-0630

Date:____________________

Dear parent/guardian of :

The University of Colorado Health Sciences Center wishes to thank you for participating in the survey of soil arsenic exposure conducted this summer.

Your child's urine arsenic level was: ______ng/ml–a concentration that is considered normal. Health experts have determined that a safe level for urine arsenic is 0 – 30 nanograms per milliliter (ng/ml).

If you have any questions concerning your test results, or if you want more information about the study or exposure to arsenic in soil, please call our project director, Kristina Kaparich, at 303-315-7999.

Sincerely,

JIM RUTTENBER, Ph.D., M.D.
Principal Investigator

Date:____________________

Dear parent/guardian of :

The University of Colorado Health Sciences Center wishes to thank you for participating in the survey of soil exposure conducted this summer.

Your child's results showed a blood lead level of _____ micrograms per deciliter (μg/dL) - a blood lead level that is considered safe. A blood lead level of 10μg/dL or greater in a child is considered elevated. Therefore, your child's blood lead level is below the level of concern.

If you have any questions concerning your test results, or if you want more information about the study or exposure to lead in soil please call our project director, Kristina Kaparich, at 303-315-7999.

We have enclosed information about the dangers of lead poisoning and how to reduce exposure to lead.

Sincerely,